

Ministry of Health

Health Care Provider Fact Sheet: Pneumococcal Conjugate Vaccine for Individuals Aged 65 Years and Older

This document is intended for informational purposes only. It is not intended to provide medical or legal advice.

Infectious agent

The bacterium *Streptococcus pneumoniae* is the cause of invasive pneumococcal disease (IPD) and a common cause of respiratory infections including community acquired pneumonia (CAP) and acute otitis media (AOM).

Pneumococcal vaccine programs in Ontario

There are three pneumococcal vaccine programs in Ontario:

- 1. Routine vaccination program for children aged 6 weeks to 4 years
- 2. Routine vaccination program for individuals aged 65 years and older
- 3. High risk vaccination program for individuals aged 6 weeks and older with certain medical or non-medical conditions who are at high risk for IPD

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 increased 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* may result in bronchitis, otitis media, sinusitis or invasive disease when *S. pneumoniae* invades 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 co-morbidities.

Vaccine	Pneumococcal Conjugate 20-valent
Vaccine abbreviation	Pneu-C-20
Vaccine name	Prevnar 20
Manufacturer	Pfizer
Protects against	IPD and pneumonia
<i>Streptococcus</i> pneumoniae serotypes	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
Route of administration	Intramuscular Injection (IM)
Package format	10 prefilled syringes
Package size (cm)	12.45 (l) x 9.91 (w) x 5.33 (h)
Eligibility Criteria	Individuals aged 65 years and older

Publicly funded vaccine for individuals aged 65 years and older

Eligibility

Adults aged 65 years and older who have not completed or have not received all eligible publicly funded pneumococcal vaccine(s) (e.g., Pneu-P-23 and/or Pneu-C-13) are eligible for immunization with Pneu-C-20 vaccine according to appropriate age and high risk criteria (Table 1, Table 2 and Table 3). Additional (catch-up) doses of Pneu-C-20 for those who have received all eligible publicly funded pneumococcal immunizations will be considered for future programming.

Recommendations for use

The following schedules only take into consideration doses of publicly funded pneumococcal vaccines received. Individuals remain eligible for publicly funded pneumococcal vaccines regardless of receipt of privately purchased pneumococcal vaccines. Health care providers should take an individual's complete pneumococcal immunization history into consideration when determining if additional doses are recommended.

Eligible age group	Risk of IPD	Recommended schedule	Eligible vaccine
	Low risk	See Table 2	Pneu-C-20
65 years and older	High risk	See Table 2	Pneu-C-20
	Post HSCT	See Table 2 and Table 3	Pneu-C-20

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

• HSCT: hematopoietic stem cell transplant recipients

Table 2: Schedules for Pneu-C-20 for those aged ≥65 years according to prior pneumococcal immunization

Risk of	History of publicly funded		Recommended # of Pneu-C-20	
IPD	Pneu-P-23	Pneu-C-13	dose(s) required and intervals	
	0 doses	Not eligible	1 dose	
Low risk	1 dose at age ≥65 years	Not eligible	None	
High risk ▲ See criteria 1 to 7 in Table 4	0 to 3 doses	0 doses	1 dose, 1 year after last dose of Pneu-	
	0 to 2 doses	1 dose	last dose of Pneu-C-13 (if applicable)	
	3 doses, with at least 1 dose at age ≥65 years	1 dose	None	
High risk ▲	0 to 2 doses	Not eligible	1 dose	
See criteria 8 to 9 in Table 4	3 doses, with at least 1 dose at age ≥65 years	Not eligible	None	

Risk of	History of publicly funded		Recommended # of Pneu-C-20	
IPD	Pneu-P-23	Pneu-C-13	dose(s) required and intervals	
High risk ▲ See criteria 10 to 17 in Table 4	0 to 1 dose	Not eligible	1 dose, 1 year after last dose of Pneu- P-23 (if applicable)	
	2 doses, with at least 1 dose at age ≥65 years	Not eligible	None	
Post HSCT	0 to 3 doses	0 doses or incomplete series	See Table 3 Dose(s) of Pneu-C-20 should be given 1 year after last dose of Pneu-P-23 (if applicable)	
	0 to 2 doses	Completed series	1 dose, 1 year after last dose of Pneu- P-23 (if applicable) and 8 weeks after last dose of Pneu-C-13	
	3 doses, with at least 1 dose at age ≥65 years	Completed series	None	

Notes:

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

- Pneu-P-23: pneumococcal polysaccharide 23-valent vaccine (Pneumovax 23)
- Pneu-C-13: pneumococcal conjugate 13-valent vaccine (Prevnar 13)

Table 3: Schedule for Pneu-C-20 for HSCT recipient aged ≥65 years who have not completed or have not started their Pneu-C-13 vaccine series post-transplant

History of publicly funded Pneu-C-13 post HSCT	Recommended # of Pneu-C-20 doses required to complete series and intervals
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-transplant and 6-12 months after 3 rd dose
1 dose post HSCT (1 st dose)	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-transplant and 6-12 months after 3 rd dose

History of publicly funded Pneu-C-13 post HSCT	Recommended # of Pneu-C-20 doses required to complete series and intervals
2 doses post HSCT (1 st and 2 nd doses)	3 rd dose, 4 weeks after 2 nd dose 4 th dose, 12-18 months post-transplant and 6-12 months after 3 rd dose
3 doses post HSCT (1 st , 2 nd and 3 rd dose)	4 th dose, 12-18 months post-transplant and 6-12 months after 3 rd dose

• If an individual started their immunization series with one Pneu-C (e.g., Pneu-C-13), it is acceptable to complete the series with another Pneu-C (e.g., Pneu-C-20).

Table 4: List of high-risk criteria that increases an individual's 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)

Risk of IPD	Previous publicly funded vaccine	Interval to Pneu-C-20 vaccine	
High	Pneu-C-13	8 weeks minimum, except post HSCT See Table 3 for post HSCT intervals	
risk▲	Pneu-P-23	1 year recommended 8 weeks, if rapid completion is required	
All	Vaccines not listed above	Pneu-C-20 vaccine may be given at the same time with other vaccines, or at any time before or after other vaccines.	
		If given by injection at the same time, 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.	

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

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.

Adverse events

Mild to moderate reactions are more commonly seen including:

- · 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 your local <u>public health</u> <u>unit</u>.

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 <u>Ontario AEFI Reporting Form</u>. A list of public health units is available at: <u>www.health.gov.on.ca/en/common/system/services/phu/locations.aspx</u>.

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 event felt to be 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

NACI recommends a 15-minute post-vaccination observation period, as specified in the <u>Canadian Immunization Guide</u> (CIG). If there is a specific concern about possible vaccine allergy, 30 minutes is a safer interval.

Record of immunization

Each vaccine recipient should be provided with a permanent personal immunization record, the Yellow Immunization Card. Please write "Prevnar 20" 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

Individuals 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

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