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.

The previous older adult and high-risk fact sheets are no longer available. This fact sheet will include information related to the adult high-risk pneumococcal program and the older adult pneumococcal program.

The tables in the appendices have been updated and an immunization decision flowchart has been included.

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

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).

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* 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.

Pneumococcal vaccines are 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	This vaccine is no longer publicly funded. Individuals previously eligible for this vaccine should receive either Pneu-C-15 or Pneu-C-20 depending if the individual is at low or high risk for IPD.
	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 of age and older at high risk for IPD and individuals ≥65 years of age at low risk for IPD.
Pneumococcal polysaccharide (Pneu-P)	Pneumovax 23	Pneu-P-23	This vaccine is no longer publicly funded. Individuals previously eligible for this vaccine should receive Pneu-C-20.

Publicly funded vaccines for adults aged 18 years and older

The pneumococcal conjugate (Pneu-C) vaccine that is available for individuals aged 18 years and older per program eligibility is **Prevnar 20** (Pneu-C-20).

For additional information see Table 1: Pneu-C-20 vaccine available in the Appendices.

Vaccine preparation and administration

See the individual vaccine product monographs for step-by-step directions on administration and expiry dates. To ensure the correct volume is accurately drawn up, refer to Table 1 in the Publicly Funded Immunization Schedules for Ontario for assistance in selecting appropriate needle length and gauge.

Vaccine storage and handling

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

Recommendations for use

The immunization schedules in this document 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
18 years and older	Low risk	See Table 2 and Figure 1	Pneu-C-20
	High risk⅄ except HSCT	See Table 3a, Table 3b and Table 3c and Figure 1	Pneu-C-20
	High risk - HSCT	See Table 3d and Figure 1	Pneu-C-20

⅄For a list of high-risk criteria that increase an individual's risk for IPD, see below.

- HSCT: hematopoietic stem cell transplant recipients

NOTE: Re-immunization using a same-valency conjugate vaccine following the completion of an age-appropriate schedule is not currently recommended since it is not known whether additional doses will confer an added benefit. Adults at high risk for IPD who have previously received dose(s) of Pneu-C-20 in adulthood are not eligible to receive the dose of Pneu-C-20 that is routinely recommended at 65 years of age or older.

High-risk criteria that increases risk for IPD

As indicated by the National Advisory Committee on Immunization (NACI), the following medical or non-medical conditions increases an individuals' 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

Vaccine	Minimum intervals
Pneu-C and Pneu-C	8 weeks minimum, except post HSCT (See Table 4 for post HSCT intervals)
Pneu-P-23 and Pneu-C	1 year minimum

Vaccine	Minimum intervals
Vaccines not listed above	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-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, provincial surveillance in Ontario and national surveillance coordinated by Health Canada and the Public Health Agency of Canada ensures ongoing monitoring of vaccine safety.

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 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 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 Canadian Immunization Guide (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" (if Pneu-C-20 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

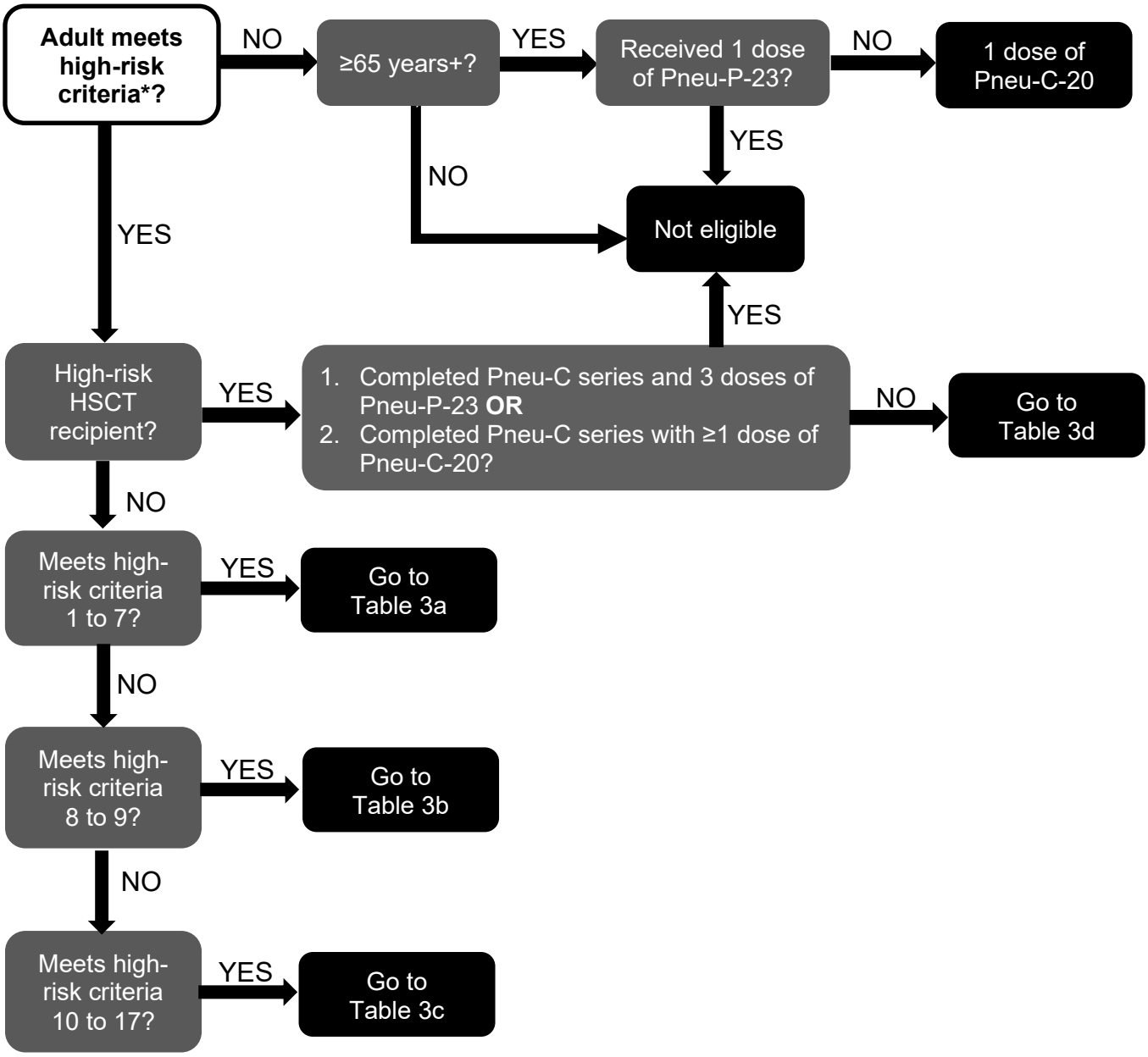
NACI and the Ontario Immunization Advisory Committee (OIAC) provides recommendations on the use of pneumococcal vaccines. Individuals who are not eligible for publicly funded Pneu-C-20 vaccines can privately purchase pneumococcal conjugate vaccines.

Appendices

Table 1: Pneu-C-20 vaccine

Vaccine	Pneumococcal Conjugate 20-valent
Vaccine abbreviation	Pneu-C-20
Vaccine name	Prevnar 20
Manufacturer	Pfizer
Protects against	IPD and pneumonia
***Streptococcus* 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) **L x W x H**	12.45 x 9.91 x 5.33
Specific storage considerations	Syringes should be stored **horizontally** to minimize the re-dispersion time.
Product monograph	Prevnar 20
Eligibility Criteria	Individuals 6 weeks and older at high-risk for IPD (high-risk) and 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 chronic care facilities or wards, 18. Hematopoietic stem cell transplant (HSCT) (recipient)

Table 2: PNEU-C-20 vaccination for adults aged ≥18 years at LOW-RISK for IPD

Adult's current age	# of previously received Pneu-P-23 doses	# of Pneu-C-20 doses recommended
18 to 64 years	0 doses	0 doses
≥65 years	0 doses	1 dose
	1 dose	0 doses

Table 3: PNEU-C-20 vaccination for adults aged ≥18 years 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	N/A	1 dose$^{\delta}$
	2 doses	N/A	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
≥65 years	0 to 3 doses	0 doses	1 dose$^{\delta}$
	0 to 2 dose	1 dose of Pneu-C-13	1 dose$^{\delta}$
	3 doses	1 dose of Pneu-C-13	0 doses
	0 to 3 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 Pneu-P-23 doses	# of Pneu-C-20 doses recommended
18 to 64 years	0 to 1 dose	1 dose$^{\delta}$
	2 doses	0 doses
≥65 years	0 to 2 doses	1 dose$^{\delta}$
	3 doses	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 chronic care facilities or wards

Adult's current age	# of previously received Pneu-P-23 doses	# of Pneu-C-20 doses recommended
18 to 64 years	0 doses	1 dose
	1 dose	0 doses
≥65 years	0 to 1 doses	1 dose$^{\delta}$
	2 doses	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 years

# of previously received doses of Pneu-C[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 of Pneu-C, if 0 to 2 doses of Pneu-P-23 previously received **OR** 0 doses, if 3 doses of Pneu-P-23 previously received
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) vaccine can be used