

**Ministry of Health**

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June 20, 2025

Dear Health Care Provider,

This letter is to inform you of an update to the pediatric component of Ontario's publicly funded pneumococcal vaccine program. This updated eligibility can be implemented immediately given supply and current use of Pneu-C-20 as part of the Ontario immunization program.

Children who are 17 years of age and younger with certain medical and non-medical conditions that increase their risk for invasive pneumococcal disease (IPD), and who have previously completed their immunization schedule with pneumococcal 13-valent conjugate (Pneu-C-13) vaccine, will be eligible for one dose of pneumococcal 20-valent conjugate (Pneu-C-20) vaccine. Please note, that eligibility for the adult pneumococcal program remains the same.

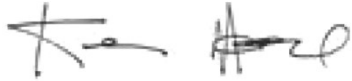
Please refer to the following attachments for additional information:

- Health Care Provider Fact Sheet: Pneumococcal Conjugate Vaccines for Children Aged 6 Weeks to 17 Years
- Health Care Provider Fact Sheet: Pneumococcal Conjugate Vaccine for Adults Aged 18 Years and Older
- Vaccine Fact Sheet: Pneumococcal Vaccine Program for Individuals Aged 6 Weeks and Older

Should you or your staff have any questions, please contact your local public health unit.

We thank you for your continued support and dedication to the publicly funded immunization program, protecting Ontarians against vaccine preventable diseases.

Sincerely,

A handwritten signature in black ink, appearing to read 'K. Moore', with a stylized flourish at the end.

Dr. Kieran Michael Moore, MD, CCFP(EM), FCFP, MPH, DTM&H, FRCPC, FCAHS  
Chief Medical Officer of Health and Assistant Deputy Minister, Public Health

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)	Prenar 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.
	Prenar 20	Pneu-C-20	Individuals $\geq 6$ weeks of age and older at high risk for IPD and individuals $\geq 65$ 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 <sup>▲</sup> 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

<sup>▲</sup>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	<p>Pneu-C-20 vaccines may be given at the same time with other vaccines, or at any time before or after other vaccines.</p> <p>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.</p>

## 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](http://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 "Pneum 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**

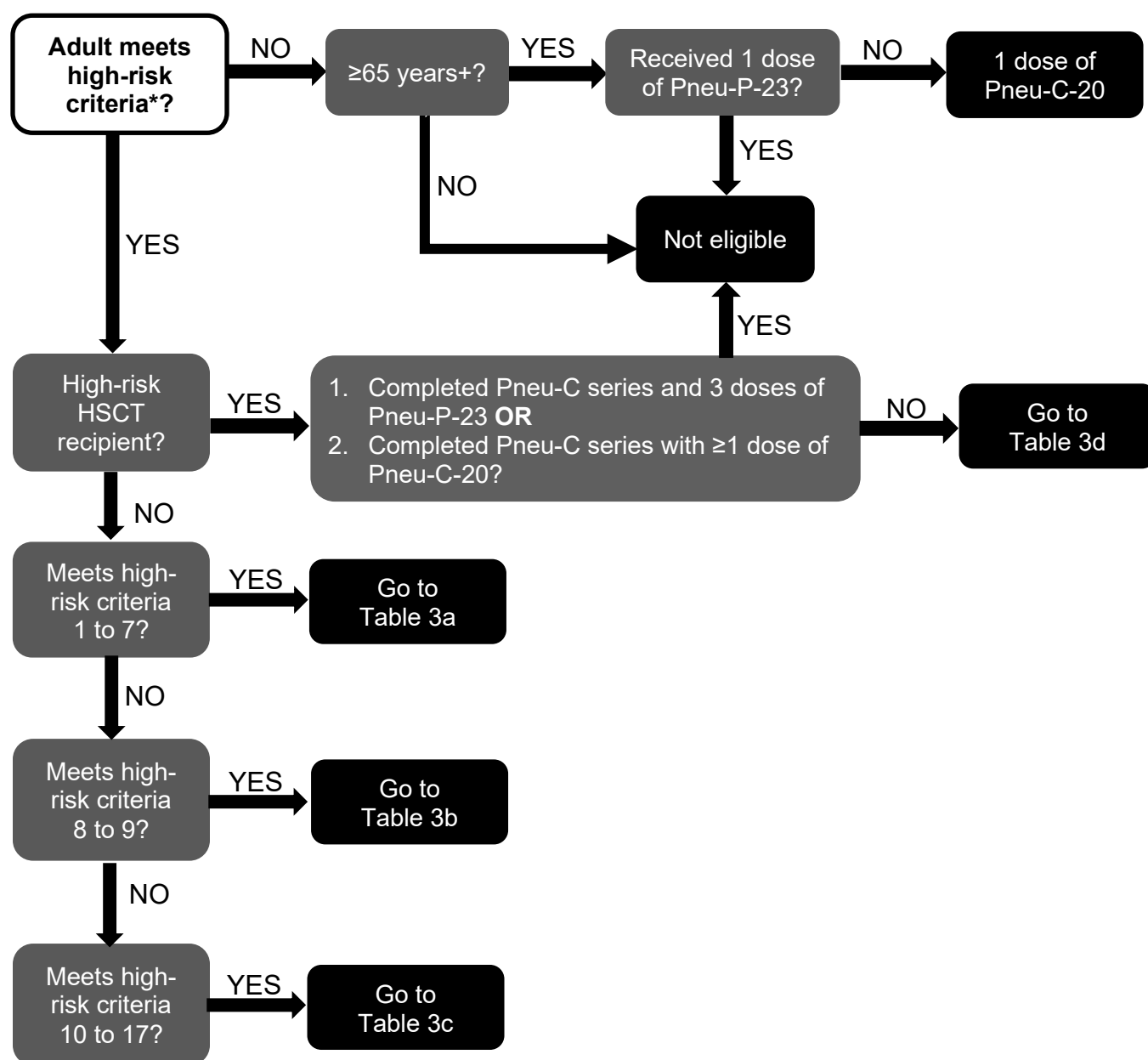
[NACI](#) and the [Ontario Immunization Advisory Committee](#) (OIAC) provides recommendations on the use of pneumococcal vaccines. Individuals who are not eligible for publicly funded Pneu-C-20 vaccines can privately purchase pneumococcal conjugate vaccines.

## 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
<i>Streptococcus pneumoniae</i> 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 <b>horizontally</b> to minimize the re-dispersion time.
Product monograph	<a href="#">Prevnar 20</a>
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  $\geq 18$  years at LOW-RISK for IPD**

<b>Adult's current age</b>	<b># of previously received Pneu-P-23 doses</b>	<b># of Pneu-C-20 doses recommended</b>
18 to 64 years	0 doses	0 doses
$\geq 65$ 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. Sick cell disease and other sick 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 <sup>δ</sup>
	2 doses	N/A	0 doses
50 to 64 years	0 to 2 doses	0 doses	1 dose <sup>δ</sup>
	0 to 1 dose	1 dose of Pneu-C-13	1 dose <sup>δ</sup>
	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 <sup>δ</sup>
	0 to 2 dose	1 dose of Pneu-C-13	1 dose <sup>δ</sup>
	3 doses	1 dose of Pneu-C-13	0 doses
	0 to 3 doses	1 dose of Pneu-C-20	0 doses

<sup>δ</sup> 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 <sup>δ</sup>
	2 doses	0 doses
≥65 years	0 to 2 doses	1 dose <sup>δ</sup>
	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 <sup>δ</sup>
	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 <sup>β</sup>	# of Pneu-C-20 doses recommended to complete series and intervals <sup>δ</sup>
0 doses post HSCT	1 <sup>st</sup> dose, 3-9 months post HSCT 2 <sup>nd</sup> dose, ≥4 weeks after 1 <sup>st</sup> dose 3 <sup>rd</sup> dose, ≥4 weeks after 2 <sup>nd</sup> dose 4 <sup>th</sup> dose, 12-18 months post HSCT and 6-12 months after 3 <sup>rd</sup> dose
1 dose post HSCT	2 <sup>nd</sup> dose, ≥4 weeks after 1 <sup>st</sup> dose 3 <sup>rd</sup> dose, ≥4 weeks after 2 <sup>nd</sup> dose 4 <sup>th</sup> dose, 12-18 months post HSCT and 6-12 months after 3 <sup>rd</sup> dose
2 doses post HSCT	3 <sup>rd</sup> dose, ≥4 weeks after 2 <sup>nd</sup> dose 4 <sup>th</sup> dose, 12-18 months post HSCT and 6-12 months after 3 <sup>rd</sup> dose
3 doses post HSCT	4 <sup>th</sup> dose, 12-18 months post HSCT and 6-12 months after 3 <sup>rd</sup> 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 <b>OR</b> 0 doses, if 3 doses of Pneu-P-23 previously received
4 doses post HSCT with ≥1 dose of Pneu-C-20	0 doses

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

<sup>β</sup> Unless noted, any Pneu-C (e.g., Pneu-C-13, Pneu-C-20) vaccine can be used

Ministry of Health

## **Vaccine Fact Sheet: Pneumococcal Vaccine Program for Individuals Aged 6 Weeks and Older**

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

### **Importance of getting immunized with pneumococcal vaccines**

Pneumococcal vaccines can prevent illness caused by many types of pneumococcal bacteria, which can cause serious and life-threatening infections like:

- Meningitis (infection of the lining of the brain)
- Septicemia (infection in the blood)
- Pneumonia (infection of the lungs)

More commonly, pneumococcal bacteria can cause:

- Otitis media (ear infections)
- Sinusitis (sinus infections)

Most pneumococcal infections are mild but can invade parts of the body that are normally bacteria-free. When this happens, a serious disease called invasive pneumococcal disease (IPD) can develop, which can cause serious symptoms, lifelong disability or even death. Meningitis, septicemia, and pneumonia caused by IPD can be fatal.

### **What pneumococcal conjugate vaccines protect against**

The pneumococcal conjugate (Pneu-C) vaccines have been approved for use by Health Canada and are safe and effective products that protect against up to 20 different types of bacteria that cause pneumococcal disease. Vaccines protect you by building antibodies against a disease. The vaccines are provided for free to eligible individuals as part of the Ontario's publicly funded immunization program.



## How pneumococcal disease is spread

Pneumococcal bacteria are very common. Many people have them in their nose and throat without getting sick, but they can still spread the bacteria through infected mucus or saliva. You may come in contact with infected mucus or saliva by:

- being near an infected person who coughs or sneezes
- having close contact with an infected person (for example, kissing or hugging)
- touching objects that were recently exposed to an infected person's mucus or saliva (such as shared utensils, cups, tissues or toys) and then rubbing your eyes, nose or mouth

## Risk of pneumococcal disease

Anyone can get pneumococcal disease, but children under 2 years old, people with certain medical conditions or other risk factors, and adults 65 years or older are at the highest risk.

## Publicly funded pneumococcal conjugate vaccines in Ontario

Type of Vaccine	Vaccine Name	Abbreviation
Pneu-C	Vaxneuvance	Pneu-C-15
	Prevnar 20	Pneu-C-20

## Eligibility criteria for Pneu-C vaccines

Eligibility	Vaccine	# of doses	Schedule
6 weeks to 4 years of age who are <b>not</b> at increased risk for IPD	Pneu-C-15	Up to 3 doses	2, 4 and 12 months of age
6 weeks to 4 years of age with certain medical and non-medical conditions that increase their risk for IPD	Pneu-C-20	Up to 4 doses	2, 4, 6 and 12 months of age
5 years of age and older with certain medical and non-medical conditions that increase their risk for IPD	Pneu-C-20	Up to 4 doses	
65 years of age and older who are <b>not</b> at increased risk for IPD	Pneu-C-20	1 lifetime dose	

Catch-up immunizations are available to those who miss their scheduled doses. Children at increased risk for IPD who have not yet received Pneu-C-20 vaccine are eligible for at least one dose of Pneu-C-20 vaccine. All other individuals who have previously received all eligible publicly funded doses of pneumococcal vaccines based on their age and risk of IPD may not be eligible to receive additional doses of pneumococcal vaccines. Speak with your health care provider to determine your vaccine eligibility and schedule.

## **Vaccine safety**

Pneu-C vaccines are approved for use by Health Canada, and they are safe. They are not only used in Canada but are used worldwide. Pneu-C vaccines have been used in Ontario's publicly funded immunization programs for more than 20 years.

Every approved vaccine must be shown to be safe and effective before it is approved for use in Canada. Once approved, vaccine safety is continuously monitored.

## **Possible reactions after receiving the vaccine**

Many people have no side effects from Pneu-C vaccines. For those that do, they are usually mild and last one to two days. Serious side effects are very rare.

Common reactions to Pneu-C vaccines may include:

- Soreness, redness and/or swelling where the vaccine was given
- Fever
- Drowsiness
- Loss of appetite
- Headache
- Muscle or joint ache
- Chills
- Fussiness (irritability) - infants only

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy before, during, or after getting vaccinated and they can take extra precautions to ensure your safety.

As with any medicine, there is an extremely rare possibility (less than one in a million people) of a life-threatening allergic reaction called anaphylaxis. Signs of anaphylaxis can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness. For this reason, it is important to remain at your health care provider's office for at least 15 minutes after you have received your Pneu-C vaccine. If anaphylaxis occurs, you will be given medicine to treat the symptoms.

Any unexpected or serious reaction to a vaccine should be reported to your health care provider or local [public health unit](#).

## **Managing side effects of the vaccine**

To help with soreness and swelling, put a cool, wet cloth over the area where you had the needle.

There is medicine to help with a fever or pain. Check with a health care provider if you are not sure what medicine or dose to take. Follow the directions on the package.

Some people with health problems, such as a weak immune system, must call their health care provider if they get a fever. If you have been told to do this, call your health care provider even if you think the fever is from the vaccine.

## **What to do if a serious problem occurs**

An allergic reaction could occur after someone leaves the place of vaccination. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get to the nearest hospital.

For other signs that concern you, call a health care provider.

Adverse reactions should be reported to a health care provider or your local [public health unit](#).

## **When not to get the vaccine or when to delay immunizations**

Speak with your health care provider if you have had a severe allergic reaction to a previous dose of pneumococcal vaccine or to any component of the vaccine including

In some cases, your health care provider may decide to postpone pneumococcal vaccine immunization until a future visit. People with minor illnesses, such as a cold, may be immunized. People who are moderately or severely ill should usually wait until they recover. Your health care provider can give you more information.

## **Vaccine record**

Your health care provider should document your immunization in your Yellow Immunization Card. Please keep your Yellow Immunization Card in a safe place and bring it with you each time you receive a vaccine from your health care provider.

## **Privately purchasing vaccine for those that are not eligible for publicly funded Pneu-C vaccine**

If you do not meet eligibility criteria for the publicly funded Pneu-C vaccine, you can speak to your health care provider to determine if the vaccine would be appropriate for you. The vaccine would need to be privately purchased; however, if you have a private insurance plan, you may connect with them to determine if Pneu-C vaccine is covered.

Ministry of Health

## Health Care Provider Fact Sheet: Pneumococcal Conjugate Vaccines 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.

**NEW: Children 6 weeks to 17 years who are at high risk of IPD that have completed their Pneu-C-13 immunization series are now eligible to receive one dose of Pneu-C-20.**

To determine the appropriate immunization schedule, refer to Figure 1: Immunization decision flowchart in the Appendices.

### 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)	Prenar 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.
	Prenar 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 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
- **Prenar 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

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 group	Risk of IPD	Recommended schedule	Eligible vaccine
Starting at 2 months of age	Low risk	2, 4, and 12 months of age* See Table 2 and Figure 1	Pneu-C-15
Starting at 2 months of age	High risk <sup>▲</sup> Except HSCT	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 HSCT	See Table 4 and Figure 1	Pneu-C-20
<sup>▲</sup> For a list of high-risk criteria that increase an individual's risk for IPD, see below. <sup>*</sup> 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. <ul style="list-style-type: none"> <li>• HSCT: hematopoietic stem cell transplant recipients</li> </ul>			

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.

### **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
Vaccines not listed above	Pneu-C-15 <b>OR</b> 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 <b>OR</b> 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](http://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 event felt to be 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**

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 “Pneumovax 20” (if Pneu-C-20 was administered) or “Vaxneuvance” (if Pneu-C-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 Pneu-C 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**

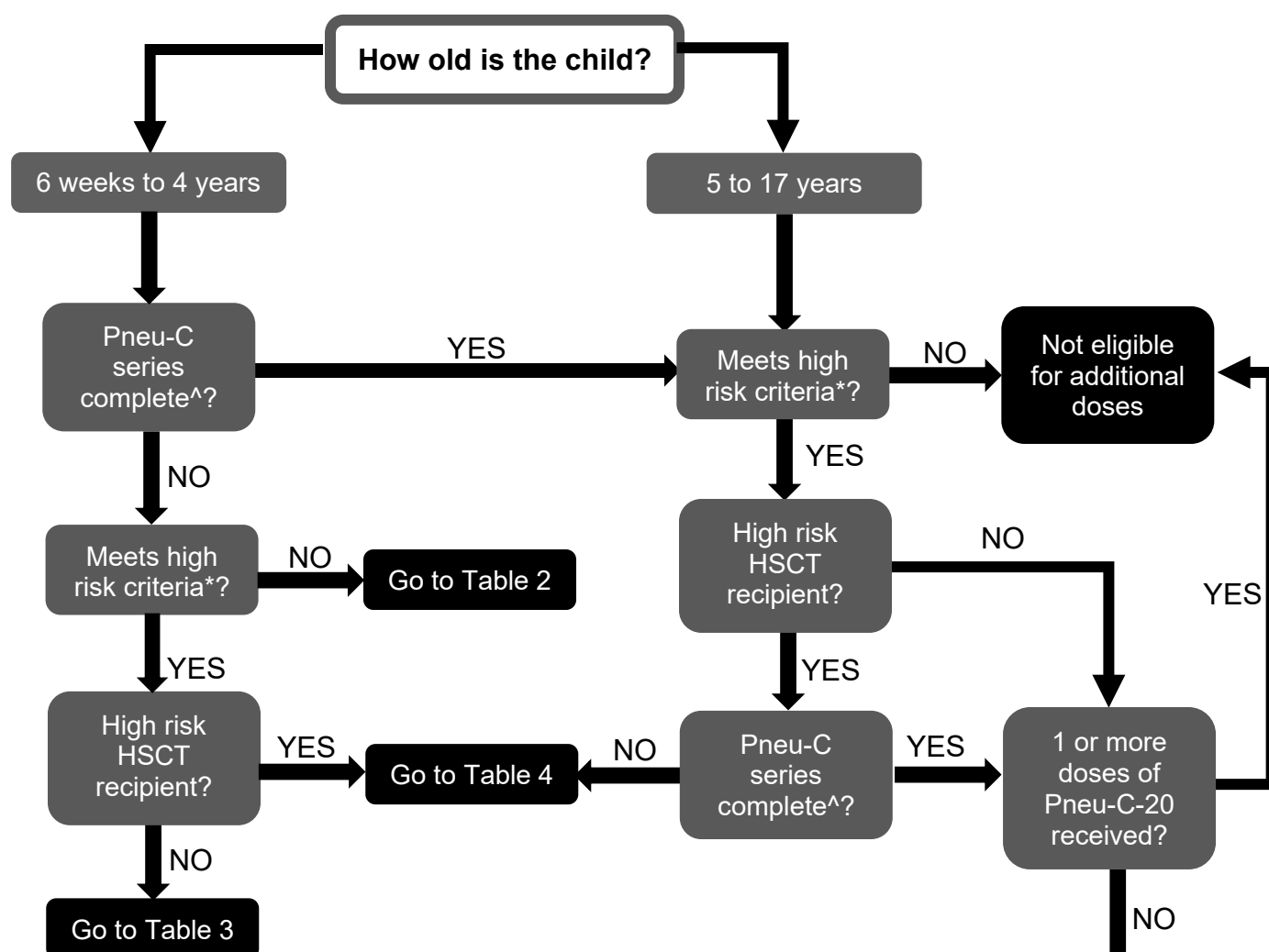
[NACI](#) provides recommendations on the use of pneumococcal conjugate vaccines. Individuals who are not eligible for publicly funded Pneu-C-15 or Pneu-C-20 can privately purchase pneumococcal conjugate vaccines.

## Appendices

Table 1: Pneu-C vaccines

Vaccine	Pneumococcal Conjugate 15-valent	Pneumococcal Conjugate 20-valent
<b>Vaccine abbreviation</b>	Pneu-C-15	Pneu-C-20
<b>Vaccine name</b>	Vaxneuvance	Prevnar 20
<b>Manufacturer</b>	Merck	Pfizer
<b>Protects against</b>	IPD	IPD
<b><i>Streptococcus pneumoniae</i> serotypes</b>	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
<b>Dosage</b>	0.5 mL	0.5 mL
<b>Route of administration</b>	Intramuscular Injection (IM)	Intramuscular Injection (IM)
<b>Package format</b>	1 prefilled syringe 10 prefilled syringes	10 prefilled syringes
<b>Package size (cm) L x W x H</b>	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
<b>Specific storage considerations</b>	N/A	Syringes should be stored <b>horizontally</b> to minimize the re-dispersion time.
<b>Product monograph</b>	<a href="#">Vaxneuvance</a>	<a href="#">Prevnar 20</a>
<b>Eligibility Criteria</b>	Children 6 weeks to 4 years <b>not</b> at low risk for IPD (low risk)	Individuals 6 weeks and older at high risk for IPD (high risk) and adults 65 years and older

**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**

<b>Child's current age</b>	<b># of previously received Pneu-C<sup>β</sup> doses</b>	<b># of <u>PNEU-C-15</u> dose(s) required to complete series</b>	<b>Intervals between doses<sup>γ</sup></b>
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

<sup>γ</sup> Recommended interval between doses is 2 months and the minimum is 8 weeks

<sup>β</sup> 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 <sup>^</sup> (except HSCT see Table 4)**

Child's current age	# of previously received Pneu-C <sup>β</sup> doses	# of <u>PNEU-C-20</u> dose(s) required to complete series	Intervals between doses <sup>γδ</sup>
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

<sup>^</sup> For a list of high-risk criteria that increase an individual's risk for IPD, see pages 3-4

<sup>β</sup> Unless noted any Pneu-C vaccine can be used

<sup>γ</sup> Recommended interval between doses is 2 months and the minimum is 8 weeks

<sup>δ</sup> 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**

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

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

<sup>β</sup> Unless noted any Pneu-C vaccine can be used