Ontario

Ministry of Health

# Health Care Provider Fact Sheet: Pneumococcal Conjugate Vaccines for Children Aged 6 Weeks to 4 Years

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.

## Publicly funded vaccines for children aged 6 weeks to 4 years

| 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 |
| ***Streptococcus* pneumoniae 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<br>10 prefilled syringes | 10 prefilled syringes |
| **Package size (cm)**<br>**L x W x H** | 1 syringe: 4.9 x 3.2 x 13.3<br>10 syringes: 11.4 x 5.2 x 12.4 | 12.45 x 9.91 x 5.33 |
| **Eligibility Criteria** | Children 6 weeks to 4 years **not** at increased risk for IPD (low risk) | Children 6 weeks to 4 years at increased risk for IPD (high risk) (See Table 6) |

## Eligibility

Children aged 6 weeks to 4 years 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, Table 3 and Table 4). 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.

**Table 1: Recommended schedule and vaccine eligibility for those aged 6 weeks to 4 years**

| Eligible group | Risk of IPD | Recommended schedule | Eligible vaccine |
|---|---|---|---|
| Starting at 2 months | Low risk | 2, 4, and 12 months of age<br>See Table 2 and Table 3 | Pneu-C-15 |
| Starting at 2 months | High risk⅄ Except HSCT | 2, 4, 6 and 12 months of age<br>See Table 2 and Table 4 | Pneu-C-20 |
| Starting 3-9 months post HSCT | Post HSCT | See Table 2 and Table 5 | Pneu-C-20 |

⅄ For a list of high-risk criteria that increase an individual's risk for IPD, see Table 6.

- HSCT: hematopoietic stem cell transplant recipients

**Table 2: Schedule for Pneu-C for children aged 6 weeks to 4 years at according to prior pneumococcal vaccine history**

| Risk for IPD | History of publicly funded | | Recommended # of Pneu-C dose(s) required and intervals |
|---|---|---|---|
| | Pneu-P-23 | Pneu-C-13 | |
| Low risk | Not eligible | 0 doses or incomplete series | See Table 3 |
| | Not eligible | Completed series | None |

| Risk for IPD | History of publicly funded | | Recommended # of Pneu-C dose(s) required and intervals |
|---|---|---|---|
| | Pneu-P-23 | Pneu-C-13 | |
| High risk✢ See criteria 1 to 9 in Table 4 | 0 to 2 doses | 0 doses or incomplete series | See Table 4<br>Dose(s) of Pneu-C-20 should be given 1 year after last dose of Pneu-P-23 (if applicable) |
| | 1 dose | Complete series | 1 dose of Pneu-C-20, 1 year after last dose of Pneu-P-23 and 8 weeks after last dose of Pneu-C-13 |
| | 2 doses | Complete series | None |
| High risk✢ See criteria 10 to 17 in Table 4 | 0 to 1 dose | 0 doses or incomplete series | See Table 4<br>Dose(s) of Pneu-C-20 should be given 1 year after last dose of Pneu-P-23 (if applicable) |
| | 1 dose | Complete series | None |
| Post HSCT | 0 to 2 doses | 0 doses or incomplete series | See Table 5<br>Dose(s) of Pneu-C-20 should be given 1 year after last dose of Pneu-P-23 (if applicable) |
| | 1 dose | Complete series | 1 dose of Pneu-C-20, 1 year after last dose of Pneu-P-23 and 8 weeks after last dose of Pneu-C-13 |
| | 2 doses | Complete series | None |

Notes:

✢ For a list of high-risk criteria that increase an individual's risk for IPD, see Table 6.

- Pneu-C-13: pneumococcal conjugate 13-valent vaccine (Prevnar 13)
- If a child 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-15 or Pneu-C-20).
- For children at high risk of IPD who started their immunization series with Pneu-C-13 or Pneu-C-15, it is recommended to complete the series with Pneu-C-20.

**Table 3: Schedule for PNEU-C-15 for children at LOW-RISK who have not completed or have not started their pneumococcal immunizations**

| Child's current age | History of publicly funded Pneu-C-13 | Recommended # of PNEU-C-15 dose(s) required to complete series and recommended intervals |
|---|---|---|
| 2 to 6 months | 0 doses | 1st dose at age ≥ 2 months<br>2nd dose, 2 months after 1st dose<br>3rd dose, 2 months after 2nd dose and at age ≥12 months |
| | 1 dose (1st dose) | 2nd dose, 2 months after 1st dose<br>3rd dose, 2 months after 2nd dose and at age ≥12 months |
| | 2 doses (1st and 2nd dose) | 3rd dose, 2 months after 2nd dose and at age ≥12 months |
| 7 to 11 months | 0 doses | 1st dose<br>2nd dose, 2 months after 1st dose<br>3rd dose, 2 months after 2nd dose and at age ≥12 months |
| | 1 dose (1st dose) | 2nd dose, 2 months after 1st dose<br>3rd dose, 2 months after 2nd dose and at age ≥12 months |
| | 2 doses (1st and 2nd dose) | 3rd dose, 2 months after 2nd dose and at age ≥12 months |
| 12 to 23 months | 0 doses | 1st dose<br>2nd dose, 2 months after 1st dose |
| | 1 dose (1st dose) at age <12 months | 2nd dose, 2 months after 1st dose<br>3rd dose, 2 months after 2nd dose |
| | 1 dose (1st dose) at age ≥12 months | 2nd dose, 2 months after 1st dose |
| | 1 dose (1st dose) at age <12 months + 1 dose (2nd dose) at age ≥12 months | 3rd dose, 2 months after 2nd dose |
| | 2 or more doses at age <12 months | 1 dose, 2 months after most recent dose |
| 24 to 59 months | 0 doses | 1 dose |
| | Any incomplete series | 1 dose, 2 months after most recent dose |

**Table 4: Schedule for PNEU-C-20 for children at HIGH-RISK□ (except HSCT) who have not completed or have not started their pneumococcal immunizations**

| Child's current age | History of publicly funded Pneu-C-13 | Recommended # of PNEU-C-20 dose(s) required to complete series and recommended intervals |
|---|---|---|
| 2 to 6 months | 0 doses | 1st dose at age ≥ 2 months<br>2nd dose, 2 months after 1st dose<br>3rd dose, 2 months after 2nd dose<br>4th dose, 2 months after 3rd dose and at age 12-15 months |
| | 1 dose (1st dose) | 2nd dose, 2 months after 1st dose<br>3rd dose, 2 months after 2nd dose<br>4th dose, 2 months after 3rd dose and at age 12-15 months |
| | 2 doses (1st and 2nd dose) | 3rd dose, 2 months after 2nd dose<br>4th dose, 2 months after 3rd dose and at age 12-15 months |
| 7 to 11 months | 0 doses | 1st dose<br>2nd dose, 2 months after 1st dose<br>3rd dose, 2 months after 2nd dose and at age 12-15 months |
| | 1 dose (1st dose) | 2nd dose, 2 months after 1st dose<br>3rd dose, 2 months after 2nd dose and at age 12-15 months |
| | 2 doses (1st and 2nd dose) | 3rd dose, 2 months after 2nd dose and at age 12-15 months |
| 12 to 23 months | 0 doses | 1st dose<br>2nd dose, 2 months after 1st dose |
| | 1 dose (1st dose) at age <12 months | 2nd dose, 2 months after 1st dose<br>3rd dose, 2 months after 2nd dose |
| | 1 dose (1st dose) at age ≥12 months | 2nd dose, 2 months after 1st dose |
| | 1 dose (1st dose) at age <12 months + 1 dose (2nd dose) at age ≥12 months | 3rd dose, 2 months after 2nd dose |
| | 2 or more doses at age <12 months | 1 dose, 2 months after most recent dose |

| Child's current age | History of publicly funded Pneu-C-13 | Recommended # of PNEU-C-20 dose(s) required to complete series and recommended intervals |
|---|---|---|
| 24 to 59 months | 0 doses | 1 dose |
| | Any incomplete series | 1 dose, 2 months after most recent dose |

Notes:

- For a list of high-risk criteria that increase an individual's risk for IPD, see Table 6.
- For post HSCT schedule, see Table 5

**Table 5: Schedule for Pneu-C-20 for HSCT recipient aged 6 weeks to 4 years who have not completed or have not started their Pneu-C-13 vaccine series post-transplant**

| History of publicly funded Pneu-C-13 | Recommended # of Pneu-C-20 doses required to complete series and intervals |
|---|---|
| 0 doses post HSCT | 1st dose, 3-9 months post HSCT<br>2nd dose, 4 weeks after 1st dose<br>3rd dose, 4 weeks after 2nd dose<br>4th dose, 12-18 months post-transplant and 6-12 months after 3rd dose |
| 1 dose post HSCT (1st dose) | 2nd dose, 4 weeks after 1st dose<br>3rd dose, 4 weeks after 2nd dose<br>4th dose, 12-18 months post-transplant and 6-12 months after 3rd dose |
| 2 doses post HSCT (1st and 2nd doses) | 3rd dose, 4 weeks after 2nd dose<br>4th dose, 12-18 months post-transplant and 6-12 months after 3rd dose |
| 3 doses post HSCT (1st, 2nd and 3rd dose) | 4th dose, 12-18 months post-transplant and 6-12 months after 3rd dose |

**Table 6: List of high-risk criteria that increases a child'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 chronic care facilities or wards
18. Hematopoietic stem cell transplant (HSCT) (recipient)

**Table 7: Intervals between vaccines**

| Risk of IPD | Previous publicly funded vaccine | Interval to Pneu-C vaccine |
|---|---|---|
| High risk⅄ | Pneu-C-13 | 8 weeks minimum, except post HSCT<br>See Table 5 for post HSCT intervals |
| | Pneu-P-23 | 1 year minimum |
| All | 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.<br>If Pneu-C-15 **OR** Pneu-C-20 vaccines 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. |

⅄For a list of high-risk criteria that increase an individual’s risk for IPD, see Table 6.

## 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 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) 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 vaccine 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 and 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

The National Advisory Committee on Immunization (NACI) provides recommendations on the use of pneumococcal vaccines. Individuals who are not eligible for publicly funded Pneu-C-15 or Pneu-C-20 vaccines can privately purchase pneumococcal conjugate vaccines.