

# Pneumococcal Vaccine, 20-valent Conjugate (Pneu-C20): Prevnar 20

## BIOLOGICAL PAGE

<b>Section 7</b>	Biological Product Information	<b>Standard # 07.293</b>
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	PREVNAR 20 Pneumococcal 20-valent Conjugate Vaccine (Pneu-C20)
<b>Manufacturer</b>	Pfizer Canada Inc.
<b>Biological Classification</b>	Inactivated: Conjugate
<b>Indications for Provincially Funded Vaccine</b>	<ul style="list-style-type: none"> <li>Individuals 65 years of age and older who have not received a dose of Pneumo-P on or after 65 years of age or a dose of Pneumococcal 20-valent conjugate vaccine (Pneu-C20) at any age.</li> <li>Individuals 2 months of age to 17 years of age who belong to 1 or more of the groups at increased risk for Invasive Pneumococcal Disease (IPD).</li> <li>Individuals 18 years of age and older who belong to 1 or more of the groups at increased risk for IPD and did not receive the previously recommended doses of pneumococcal conjugate and polysaccharide vaccines.</li> <li>To determine eligibility, refer to the Pneu-C20 Eligibility for Populations at Increased Risk of Invasive Pneumococcal Disease (IPD) algorithm in <a href="#">Appendix A</a>.</li> </ul> <p><b>Note:</b> If Pneu-C20 is refused, Pneu-C15 may be offered.</p> <p><b>Populations at Increased Risk for Invasive Pneumococcal Disease (IPD):</b></p> <p>Populations with sustained high rates of IPD:</p> <ul style="list-style-type: none"> <li>Residents of continuing care homes and senior supportive living accommodations.</li> <li>First Nations, Métis, and Inuit individuals, regardless of where they live.</li> </ul> <p>Individuals with the following medical conditions (See <a href="#">Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression</a>):</p> <ul style="list-style-type: none"> <li>Asplenia/hyposplenism (functional or anatomic).</li> <li>Chronic cardiac disease (including congenital heart disease and cyanotic heart disease).</li> <li>Chronic cerebral spinal fluid (CSF) leak.</li> <li>Chronic liver disease (including biliary atresia, fatty liver, hepatitis B and C and hepatic cirrhosis due to any cause).</li> <li>Chronic neurologic condition that may impair clearance of oral secretions.</li> <li>Chronic pulmonary disease (including asthma requiring medical treatment within the last 12 months, regardless of whether they are on high dose steroids).</li> <li>Chronic renal disease, including nephrotic syndrome, or on dialysis.</li> <li>Cochlear implants (candidates and recipients).</li> <li>Congenital 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.</li> <li>Diabetes mellitus.</li> </ul>

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- Hematopoietic stem cell transplant (HSCT) and/or CAR T-cell therapy recipients. See [Immunization for Child HSCT Transplant Recipients](#) or [Immunization for Adult HSCT Transplant Recipients](#).
  - HIV infection.
  - Immunosuppressive therapy including:
    - Long term use of long-term corticosteroids,
    - Chemotherapy,
    - Radiation therapy,
    - Biologic and non-biologic immunosuppressive therapies, for:
      - Inflammatory arthropathies, example, systemic lupus erythematosus (SLE), rheumatoid or juvenile arthritis,
      - Inflammatory dermatological conditions, example, psoriasis, severe atopic dermatitis, and eczema, and
      - Inflammatory bowel disease, example, Crohn's disease, ulcerative colitis
- Note: Individuals prescribed eculizumab (Soliris®) or other complement C5 inhibitors are at increased risk of serious infections, especially with encapsulated bacteria, such as *Streptococcus pneumoniae*; therefore, they should receive Pneu-C20 vaccine at least two weeks before receiving the first doses of complement C5 inhibitors if possible.
- Malignant hematologic disorders (affecting the bone marrow or lymphatic system) including leukemia, lymphoma, Hodgkin's disease, and multiple myeloma.
  - Malignant solid organ tumors either currently or within last 5 years.
  - Sickle-cell disease and other hemoglobinopathies.
  - Solid organ or islet transplant (SOT) candidates and recipients. See [Immunization for Adult SOT Candidates and Recipients](#), [Immunization for Children Expecting SOT Before 18 Months of Age](#) or [Immunization for Children Expecting SOT After 18 Months of Age](#)

### Individuals who:

- Have an alcohol use disorder
- Use illicit drugs
- Smoke or vape
- Have poor indoor air quality in the home (including, but not limited to, secondhand smoke, wood fired stoves)
- Are experiencing houselessness
  - Definition: At the time of diagnosis, the individual did not have an address or home (apartment, townhouse, etc.). This would include people staying in shelters, cars, etc.

### Note:

- Individuals 25 months of age and older who have already received at least 1 dose of Pneu-C20 are not eligible for another dose.
  - Reimmunization using a same-valency conjugate vaccine is not currently recommended as it is not known whether additional doses will provide additional benefit.
- With the exception of adult HSCT and SOT recipients, individuals 18 years of age and older who previously received another pneumococcal conjugate vaccine series, and the recommended dose(s) of Pneumo-P are considered complete and are not eligible for Pneu-C20.
- If a series is interrupted due to IPD, continue the series once the individual has recovered.
  - Previous IPD does not confer immunity or preclude immunization with pneumococcal conjugate vaccine.
- For disease investigation and reporting requirements, see to [Alberta public health disease management guidelines : pneumococcal disease, invasive \(IPD\)](#).

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Serology	N/A
Schedule	<p><b>Schedule for children 6 weeks of age to 17 years of age at high-risk for IPD</b></p> <p>Starting immunization at:</p> <p>2 months up to and including 6 months of age (4 doses)</p> <ul style="list-style-type: none"> <li>• Dose 1: 2 months of age</li> <li>• Dose 2: 4 months of age</li> <li>• Dose 3: 6 months of age</li> <li>• Dose 4 (reinforcing): 12 months of age and a minimum of 8 weeks after the previous dose.</li> </ul> <p>7 months up to and including 11 months of age (3 doses)</p> <ul style="list-style-type: none"> <li>• Dose 1: day 0</li> <li>• Dose 2: 8 weeks after dose 1</li> <li>• Dose 3 (reinforcing): 12 months of age and a minimum of 8 weeks after the previous dose</li> </ul> <p>12 months up to and including 24 months of age (2 doses)</p> <ul style="list-style-type: none"> <li>• Dose 1: day 0</li> <li>• Dose 2: 8 weeks after dose 1</li> </ul> <p>25 months and older</p> <ul style="list-style-type: none"> <li>• 1 dose</li> </ul> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• Dose 1 may be administered to early as 6 weeks of age.</li> <li>• The recommended interval between doses 1, 2 and/or 3 for children younger than 1 year of age is 8 weeks. However, the interval may be shortened to 4 weeks.</li> <li>• The reinforcing dose is to be given at 12 months of age or older and at least 8 weeks from previous dose.</li> <li>• The minimum interval between doses for children receiving immunization after 12 months of age is 8 weeks.</li> </ul> <p>For children who have received HSCT and/or CAR T-cell therapy see - <a href="#">Immunization for Child HSCT Transplant Recipients</a></p> <p>For children who have received SOT see – <a href="#">Immunization for Children Expecting SOT Before 18 Months of Age</a> or <a href="#">Immunization for Children Expecting SOT After 18 Months of Age</a></p> <p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• High-risk children who started a series with another pneumococcal conjugate vaccine should complete their series with Pneu-C20. <ul style="list-style-type: none"> <li>○ Previous doses will be counted, and the series will not be restarted.</li> <li>○ Children who have completed a vaccine series appropriate for age that includes at least one dose of Pneu-C20 are considered complete.</li> </ul> </li> <li>• Children at an increased risk of developing IPD who previously completed a series with another pneumococcal conjugate vaccine and/or received the recommended doses of Pneumo-P vaccine are eligible for 1 dose of Pneu-C20. <ul style="list-style-type: none"> <li>○ This dose should be given a minimum of 8 weeks since the last pneumococcal conjugate vaccine dose and a minimum of 1 year since their last dose of Pneumo-P vaccine.</li> </ul> </li> </ul>

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### Interrupted Schedule for High-Risk Children (4 dose series)

# of Previous Doses	Completion of Primary Series (4 to 8 weeks apart)	Reinforcing Dose (given in the second year of life at least 8 weeks after last pneumococcal conjugate dose)
3 months up to and including 6 months at re-presentation		
0 previous doses	3 doses	1 dose
1 previous dose	2 doses	1 dose
2 previous doses	1 dose	1 dose
7 months up to and including 11 months at re-presentation		
0 previous doses	2 doses	1 dose
1 to 2 previous doses prior to 7 months	1 dose	1 dose
12 months up to and including 24 months at re-presentation		
0 to 1 previous doses prior to 12 months	1 dose	1 dose
2 to 3 previous doses prior to 12 months	Primary series complete	1 dose
1 previous dose at 12 months of later	Primary series complete	1 dose
25 months up to and including 59 months at re-presentation		
0 doses Pneu-C20	1 dose	
6 years up to and including 17 years at re-presentation		
0 doses Pneu-C20	1 dose	

### Adults 18 years of age and older at risk for IPD

Individuals with the following medical conditions, see [Appendix A](#) :

Are eligible for 1 dose of Pneu-C20 if they have not received at least 2 doses of Pneumo-P and one dose of Pneu-C13, or a previous dose of Pneu-C20. See [Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression](#).

- Asplenia/hyposplenism (functional or anatomic).
- Chronic renal disease, including nephrotic syndrome, on dialysis.
- Congenital 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.
- HIV infection.

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- Immunosuppressive therapy including:
  - Long-term use of corticosteroids,
  - Chemotherapy (undergoing or anticipating),
  - Radiation therapy (undergoing or anticipating),
  - Biologic and non-biologic immunosuppressive therapies, for:
    - Inflammatory Arthropathies, example, systemic lupus erythematosus (SLE), rheumatoid or juvenile arthritis,
    - Inflammatory Dermatological Conditions, example, psoriasis, severe atopic dermatitis, and eczema, and
    - Inflammatory Bowel Disease, example, Crohn's disease, ulcerative colitis.
- Malignant hematologic disorders (affecting the bone marrow or lymphatic system) including leukemia, lymphoma, Hodgkin's disease and multiple myeloma.
- Malignant solid organ tumors either currently or within past 5 years.
- Sickle-cell disease and other hemoglobinopathies.

**Individuals in the following categories, see [Appendix A](#) :**

Are eligible for 1 dose of Pneu-C20 if they have not received at least 1 dose of Pneumo-P or a previous dose of Pneu-C20.

- Populations with sustained high rates of IPD:
  - Residents of continuing care homes and supportive living accommodations.
  - First Nations, Métis, and Inuit peoples, regardless of where they live.
- Individuals with the following medical conditions:
  - Chronic cardiac disease (including congenital heart disease and cyanotic heart disease).
  - Chronic cerebral spinal fluid (CSF) leak.
  - Chronic liver disease (including biliary atresia, fatty liver, hepatitis B and C and hepatic cirrhosis due to any cause).
  - Chronic neurologic condition that may impair clearance of oral secretions.
  - Chronic pulmonary disease (including asthma requiring medical treatment within the last 12 months regardless of whether they are on high dose steroids).
  - Cochlear implants (candidates and recipients).
  - Diabetes mellitus.
- Individuals who:
  - Have an alcohol use disorder
  - Use illicit drugs
  - Smoke or vape
  - Have poor indoor air quality in the home (including, but not limited to, second-hand smoke, and wood fired stoves)
  - Are experiencing houselessness.

### **Adult Hematopoietic stem cell transplant (HSCT) and/or CAR T-cell therapy and/or Solid Organ Transplant**

- See [Immunization for Adult HSCT Transplant Recipients](#).
- See [Immunization for Adult SOT Candidates and Recipients](#).

**Adults 65 years of age and older, see [Appendix A](#) :**

Are eligible for 1 dose of Pneu-C20 if they have not received a Pneumo-P vaccine dose on or after 65 years of age or a dose of Pneu-C20 at any age.

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	<p><b>Note:</b></p> <ul style="list-style-type: none"> <li>• Individuals should wait a minimum of 8 weeks since their last pneumococcal conjugate vaccine dose and a minimum of 1 year since their last Pneumo-P vaccine before receiving Pneu-C20.</li> <li>• Administer vaccine at least 14 days before splenectomy or initiation of immunosuppressive therapy.</li> <li>• Wait at least 3 months from the end of immunosuppressive therapy and administration of the vaccine if the vaccine cannot be administered before initiation of immunosuppressive therapy.</li> <li>• Administer the vaccine as soon as possible if immunosuppression is long-term/ongoing and/or for those with malignant solid organ tumors or malignant hematological disorders currently undergoing immunosuppressive therapy.</li> </ul>
Preferred Use	N/A
Dose	0.5 mL
Route	Intramuscular injection
Contraindications/ Precautions	<p><b>Contraindications</b></p> <ul style="list-style-type: none"> <li>• Known severe hypersensitivity to any component of Pneu-C20 including diphtheria toxoid.</li> <li>• Anaphylaxis to a previous dose of vaccine containing pneumococcal antigen.</li> </ul> <p><b>Precautions</b></p> <ul style="list-style-type: none"> <li>• Pneu-C20 will not protect against <i>S. pneumoniae</i> serotypes not included in the vaccine.</li> </ul>
Possible Reactions	<p><b>Common:</b></p> <ul style="list-style-type: none"> <li>• Pain, redness, swelling at injection site</li> <li>• Irritability</li> <li>• Drowsiness / increased sleep</li> <li>• Decreased appetite</li> <li>• Fever</li> <li>• Muscle pain</li> <li>• Fatigue</li> <li>• Headache</li> <li>• Joint pain</li> <li>• Chills</li> <li>• Vomiting</li> <li>• Diarrhea</li> <li>• Rash.</li> </ul> <p><b>Uncommon:</b></p> <ul style="list-style-type: none"> <li>• Hypersensitivity reaction, including face edema, dyspnea and bronchospasm</li> <li>• Angioedema</li> <li>• Vaccination-site pruritus, lymphadenopathy, vaccination-site urticaria</li> <li>• Urticaria or urticaria like rash</li> <li>• Seizures.</li> </ul> <p><b>Rare:</b></p> <ul style="list-style-type: none"> <li>• Anaphylaxis</li> <li>• Allergic reaction</li> <li>• Vaccination site hypersensitivity</li> </ul>

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	<ul style="list-style-type: none"> <li>As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.</li> </ul>
<b>Pregnancy</b>	<ul style="list-style-type: none"> <li>Safety during pregnancy has not been established in humans. <ul style="list-style-type: none"> <li>Individuals who are pregnant can be immunized with pneumococcal vaccines.</li> <li>There is no evidence to suggest a risk to the infant, fetus or pregnancy from immunization.</li> </ul> </li> </ul>
<b>Lactation</b>	<ul style="list-style-type: none"> <li>Safety during lactation has not been established in humans. <ul style="list-style-type: none"> <li>It is not known whether vaccine antigens or antibodies are excreted in human milk.</li> <li>Individuals who are breast/chest feeding can be immunized with pneumococcal vaccines.</li> <li>There is no evidence to suggest a risk to the infant, fetus or pregnancy from immunization.</li> </ul> </li> </ul>
<b>Composition</b>	<p>Each 0.5 mL dose contains:</p> <ul style="list-style-type: none"> <li>Active substances individually linked to the non-toxic diphtheria (CRM<sub>197</sub>) carrier protein: <ul style="list-style-type: none"> <li>2.2 mcg of each of <i>S. pneumoniae</i> serotypes 1, 3, 4, 5, 6A, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F and 33F</li> <li>4.4 mcg of <i>S. pneumoniae</i> serotype 6B.</li> </ul> </li> <li>Nonmedicinal ingredients: <ul style="list-style-type: none"> <li>125 mcg aluminum phosphate</li> <li>100 mcg polysorbate 80</li> <li>4.4 mcg sodium chloride</li> <li>295 mcg succinic acid</li> <li>Water for injection.</li> </ul> </li> </ul>
<b>Blood/Blood Products</b>	Does not contain any blood products.
<b>Bovine/Porcine Products</b>	Does not contain any bovine or porcine products.
<b>Latex</b>	Does not contain latex.
<b>Interchangeability</b>	N/A
<b>Administration with Other Products</b>	<p>May be given at the same time as other inactivated and live vaccines.</p> <ul style="list-style-type: none"> <li>Use a separate needle and syringe for each vaccine.</li> <li>The same limb may be used, if necessary, but use different sites on the limb.</li> </ul>
<b>Appearance</b>	A homogenous white suspension
<b>Storage</b>	<ul style="list-style-type: none"> <li>Store between 2°C and 8°C.</li> <li>Store syringes horizontally in the fridge to minimize re-dispersion time.</li> <li>Administer as soon as possible once removed from cold chain.</li> <li>Do not freeze.</li> </ul>
<b>Vaccine Code</b>	PNEU-C20
<b>Antigen Code</b>	PNEUMO-C
<b>Licensed for</b>	Individuals 6 weeks of age and older.
<b>Notes</b>	<ul style="list-style-type: none"> <li>2024 June 24: Prevnar 20™ Pneumococcal Conjugate (20 valent) - Introduced into the routine immunization program for high-risk individuals 2 months of age and older who belong to 1 or more of the groups at increased risk for IPD and for all individuals 65 years and older who have not previously received a dose of Pneumo-P or Pneu-C20.</li> </ul>

	PREVNAR 20 Pneumococcal 20-valent Conjugate Vaccine (Pneu-C20)
	<ul style="list-style-type: none"><li>2024 September 6: To clarify that individuals 65 years of age and older who have not received a dose of Pneumo-P on or after 65 years of age or a dose of Pneu-C20 at any age, are eligible for a dose of Pneu-C20 vaccine.</li><li>2024 November 20: To reinforce that Pneu-C20 should be given a minimum of one year after the last dose of Pneumo-P.</li></ul>
Related Resources	Pneumococcal Vaccine, 20-valent Conjugate (Pneu-C20) Information Sheet
<b>References</b> <p>Alberta Health. (2024, November) Pneumococcal Vaccine, 20-valent Conjugate: Prevnar 20. In Alberta Immunization Policy: Biological Products. Government of Alberta.</p> <p>Alberta Health. (2021, September). Pneumococcal Disease, Invasive. In Alberta Health: Disease Management Guidelines. Government of Alberta.</p> <p>Alexion Pharma GmbH. (2024, July 24) Soliris (eculizumab for injection) product monograph. Health Canada drug product database. <a href="https://pdf.hres.ca/dpd_pm/00053762.PDF">https://pdf.hres.ca/dpd_pm/00053762.PDF</a>.</p> <p>National Advisory Committee on Immunization. (2024, February 24) Public health level recommendations on the use of pneumococcal vaccines in adults, including the use of 15 valent and 20 valent conjugate vaccines. Public Health Agency of Canada.</p> <p>Pfizer Canada, email communication, May 27, 2024, and May 28, 2024.</p> <p>Pfizer Canada ULC. (2023, November 16). Prevnar 20 Pneumococcal 20-valent Conjugate vaccine. Health Canada drug product database. <a href="https://webfiles.pfizer.com/file/eaacb9cc-8b8c-4ddf-af69-93e374730387?referrer=ccb731e5-4f2d-4f4a-b2dc-e5e912145fc6">https://webfiles.pfizer.com/file/eaacb9cc-8b8c-4ddf-af69-93e374730387?referrer=ccb731e5-4f2d-4f4a-b2dc-e5e912145fc6</a>.</p> <p>Public Health Agency of Canada. (2023) Canadian Immunization Guide - Government of Canada.</p>	

# PNEU-C20 Eligibility for Populations at Increased Risk of Invasive Pneumococcal Disease (IPD)

