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

Implementation Date: June 24, 2024

Please consult the Product Monograph for further information about the product.	
	Prevnar 20™ Pneumococcal 20-valent Conjugate Vaccine (Pneu-C20)
Manufacturer	Pfizer Canada Inc.
Licensed use	Individuals 6 weeks of age and older[1]
Off-license use	None
Indications for use of provincially funded vaccine	• All individuals 65 years of age and older who have not previously received a dose of Pneumo-P or Pneumococcal 20-valent conjugate vaccine (Pneu-C20). • Individuals 2 months of age to 17 years of age who belong to one or more of the populations at increased risk for Invasive Pneumococcal Disease (IPD).[2,3] • Individuals 18 years of age and older who belong to one or more of the populations at increased risk for Invasive Pneumococcal Disease (IPD) and did not receive the previously recommended doses of pneumococcal conjugate and polysaccharide vaccines. *To determine eligibility, please refer to the eligibility algorithm*. **Populations at Increased Risk for Invasive Pneumococcal Disease (IPD)** *Populations with sustained high rates of IPD:* • Residents of continuing care homes and senior supportive living accommodations • First Nations, Métis, and Inuit peoples, regardless of where they live *Individuals with the following medical conditions:* • Asplenia/hyposplenism (functional or anatomic)[2,4] See Special Situations for Immunization – Immunization of Specific Populations • Chronic cardiac disease (including congenital heart disease and cyanotic heart disease).[2,4] • Chronic cerebral spinal fluid (CSF) leak.[2,4] • Chronic liver disease (including biliary atresia, fatty liver, hepatitis B and C and hepatic cirrhosis due to any cause).[2,4] • Chronic neurologic condition that may impair clearance of oral secretions.[2,4] • Chronic pulmonary disease (including asthma requiring medical treatment within the last 12 months regardless of whether they are on high dose steroids). [2,4] • Chronic renal disease, including nephrotic syndrome, on dialysis, or with renal transplant.[2,4]

	• Cochlear implants (candidates and recipients).[2,4]
	• 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.[2,4]
	• Diabetes mellitus.[2,4]
	• Hematopoietic stem cell transplant (HSCT) and/or CAR T-cell therapy recipients.[2,4] See - Immunization for Child Hematopoietic Stem Cell Transplant Recipients or Immunization for Adult Hematopoietic Stem Cell Transplant Recipients.
	• HIV infection.[2,4]
	• Immunosuppressive therapy including: [2–4]
	  ○ long-term use of corticosteroids,
	  ○ chemotherapy (undergoing or anticipating),
	  ○ radiation therapy (undergoing or anticipating),
	  ○ post-organ transplant therapy,
	  ○ biologic and non-biologic immunosuppressive therapies for:
	  ▪ inflammatory arthropathies, e.g., systemic lupus erythematosus (SLE), rheumatoid or juvenile arthritis,
	  ▪ inflammatory dermatological conditions, e.g., psoriasis, severe atopic dermatitis and eczema, and
	  ▪ inflammatory bowel disease, e.g., 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;*[5] therefore, they should receive Pneu-C20 at least two weeks before receiving the first doses of complement C5 inhibitors, if possible.[3]
	For additional information see: Immunization of Specific Populations.
	• Malignant hematologic disorders (affecting the bone marrow or lymphatic system) including leukemia, lymphoma, Hodgkin's disease and multiple myeloma.[2,4]
	• Malignant solid organ tumors either currently or within past 5 years
	• Sickle-cell disease and other hemoglobinopathies.[2,4]
	• Solid organ or islet transplant (SOT) candidates and recipients.[2,4] See Immunization for Children Expecting Solid Organ Transplant before 18 Months of Age (Accelerated), Immunization for Children Expecting Solid Organ Transplant at 18 Months of Age or Older (Catch-up Schedule) or Immunization for Adult Solid Organ Transplant Candidates and Recipients.
	Individuals who:
	• Have an alcohol use disorder[4]
	• Use illicit drugs[4]
	• Smoke[4] or vape

<table>
<tr><td></td><td colspan="2">

Have poor indoor air quality in the home (including, but not limited to, second-hand smoke, wood fired stoves)
Are experiencing houselessness[2,4]

Definition: At the time of immunization assessment, 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 one dose of Pneu-C20 are not eligible for another dose. Re-immunization using a same-valency conjugate vaccine is not currently recommended as it is not known whether additional doses will provide additional benefit. [3]
Individuals 18 years of age and older of age 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.
Note: Regardless of previous IPD history immunization with pneumococcal conjugate vaccine is recommended. If a series is interrupted due to IPD, the series should be continued once the individual has recovered.

For disease investigation and reporting requirements, refer to Public Health Notifiable Disease Management Guidelines – Invasive Pneumococcal Disease.[6]
</td></tr>
<tr><td>Dose</td><td colspan="2">0.5 mL[1]</td></tr>
<tr><td>Route</td><td colspan="2">Intramuscular injection[1]</td></tr>
<tr><td rowspan="6">Schedule</td><td colspan="2"></td></tr>
<tr><td colspan="2">Children at high-risk</td></tr>
<tr><td colspan="2">Starting immunization at:</td></tr>
<tr><td>2 months up to and including 6 months of age (4 doses)</td><td>❖ Dose 1: two months of age
❖ Dose 2: four months of age
❖ Dose 3: six months of age
❖ Dose 4 (reinforcing): 12 months of age and a minimum of 8 weeks after the previous dose.</td></tr>
<tr><td>7 months up to and including 11 months of age (3 doses)</td><td>❖ Dose 1: day 0
❖ Dose 2: eight weeks after dose 1.
❖ Dose 3 (reinforcing): 12 months of age and a minimum of 8 weeks after the previous dose.</td></tr>
<tr><td>12 months up to and including 24 months of age (2 doses)</td><td>❖ Dose 1: day 0
❖ Dose 2: eight weeks after dose 1</td></tr>
<tr><td>25 months and older</td><td>❖ 1 dose</td></tr>
</table>

	Children 6 weeks of age to 17 years of age at high-risk for IPD • Dose 1 may be administered to infants as early as six weeks of age.(1) • The recommended interval between doses 1, 2 and/or 3 for children younger than one year of age is eight weeks. However, the interval may be shortened to four weeks.(1) • The reinforcing dose is to be given in the second year of life (12 months of age or older) (2), and at least 8 weeks from previous dose.(1) • The minimum interval between doses for children receiving immunization after 12 months of age is eight weeks.(3) • High-risk children who started a series with another pneumococcal conjugate vaccine, should complete their series with Pneu-C20. (2,3) Previous doses will be counted and the series will not be restarted. Children who have completed a vaccine series appropriate for age that includes at least one dose of Pneu-C20 are considered complete.(2,3) • 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 one dose of Pneu-C20 if they have not yet received a dose of Pneu-C20.(2,3) It is recommended that this dose be given at least 8 weeks since the last pneumococcal conjugate vaccine dose or at least one year since their last dose of Pneumo-P. (3) For children who have received HSCT and/or CAR T-cell therapy see - Immunization for Child Hematopoietic Stem Cell Transplant Recipients. For children who received SOT - Immunization for Children Expecting Solid Organ Transplant before 18 Months of Age (Accelerated) and Immunization for Children Expecting Solid Organ Transplant at 18 Months of Age or Older (Catch-up Schedule).
	18 years of age and older at high-risk for IPD

	Individuals with the following medical conditions are eligible for one 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.
	• Asplenia/hyposplenism (functional or anatomic) See Special Situations for Immunization – Immunization of Specific Populations
	• Chronic renal disease, including nephrotic syndrome, on dialysis, or with renal transplant.
	• 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.
	• Immunosuppressive therapy including
	  ○ long-term use of corticosteroids,
	  ○ chemotherapy (undergoing or anticipating),
	  ○ radiation therapy (undergoing or anticipating),
	  ○ post-organ transplant therapy,
	  ○ biologic and non-biologic immunosuppressive therapies for:
	  ▪ inflammatory arthropathies, e.g., systemic lupus erythematosus (SLE), rheumatoid or juvenile arthritis,

	▪ inflammatory dermatological conditions, e.g., psoriasis, severe atopic dermatitis and eczema, and ▪ inflammatory bowel disease, e.g., 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. **The following individuals are eligible for one 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, wood fired stoves) • Are experiencing houselessness For adults who are hematopoietic stem cell transplant (HSCT) and/or CAR T-cell therapy recipients, refer to Immunization for Adult Hematopoietic Stem Cell Transplant Recipients. For adults who are Solid organ or islet transplant (SOT) candidates and recipients, refer to Immunization for Adult Solid Organ Transplant Candidates and Recipients. **Note:** • It is recommended that individuals wait at least 8 weeks since their last pneumococcal conjugate vaccine dose or at least one year since their last dose of Pneumo-P vaccine before receiving Pneu-C20 dose [3].
	Individuals 65 years of age and older (not included in the populations at increased risk for IPD above)

	Individuals 65 years of age and older who have not received Pneumo-P on or after 65 years of age or a dose of Pneu-C20. ❖ 1 dose [3,4] **Note:** • It is recommended that individuals wait at least 8 weeks since their last pneumococcal conjugate vaccine dose or at least one year since their last dose of Pneumo-P vaccine before receiving Pneu-C20 dose [3].
	Note: • If possible, vaccine should be administered at least 14 days before splenectomy or initiation of immunosuppressive therapy.[3] • If the vaccine cannot be administered before initiation of immunosuppressive therapy, generally a period of at least 3 months should elapse between therapy cessation and administration of the vaccine.[3] • If immunosuppression is long-term/ongoing and/or for those with malignant solid organ tumors or malignant hematological disorders currently undergoing immunosuppressive therapy, the vaccine should be administered as soon as possible.[3]
Contraindications	• Known severe hypersensitivity to any component of Pneu-C20, including diphtheria toxoid.[1] • Anaphylaxis to a previous dose of vaccine containing pneumococcal antigen.
Precautions	• Pneu-C20 will not protect against *S. pneumoniae* serotypes not included in the vaccine.[1]
Pregnancy	• Safety during pregnancy has not been established in humans.[1] • If indicated, individuals who are pregnant can be immunized with pneumococcal vaccines, as there is no evidence to suggest a risk to the infant, fetus or to the pregnancy from immunization.[3] •
Lactation	• Safety during lactation has not been established in humans, and it is not known whether vaccine antigens or antibodies are excreted in human milk.[1] However, If indicated, individuals who are breastfeeding can be immunized with pneumococcal vaccines, as there is no evidence to suggest a risk to the infant, fetus or to the pregnancy from immunization.[3]
Program Notes	• July 1, 2024 – 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 one or more of the groups at increased risk for Invasive Pneumococcal Disease (IPD) and for all individuals 65 years and older who have not previously received a dose of Pneumo-P or Pneu-C20.

References

1. Pfizer Canada ULC. Prevnar 20 Pneumococcal 20-valent Conjugate Vaccine [Internet]. 2023. Available from: https://pdf.hres.ca/dpd_pm/00065729.PDF

2. National Advisory Committe on Immunization. Recommendations for public health programs on the use of pneumococcal vaccines in children, including the use of 15-valent and 20-valent conjugate vaccines [Internet]. 2024. Available from: https://www.canada.ca/content/dam/phac-aspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-recommendations-public-health-programs-use-pneumococcal-vaccines-children-including-use-15-valent-20-valent-conjugate-vaccines/naci-statement-2024-03-11.pdf

3. National Advisory Committee on Immunization. Canadian Immunization Guide - Canada.ca [Internet]. Public Health Agency of Canada. 2023. Available from: https://www.canada.ca/en/public-health/services/canadian-immunization-guide.html

4. National Advisory Committee on Immunization. Public health level recommendations on the use of pneumococcal vaccines in adults, including the use of 15 valent and 20 valent conjugate vaccines [Internet]. 2023. Available from: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/public-health-level-recommendations-use-pneumococcal-vaccines-adults-including-use-15-valent-20-valent-conjugate-vaccines.html

5. Alexion Pharma GmbH. Soliris (eculizumab for injection) product monograph [Internet]. Available from: https://pdf.hres.ca/dpd_pm/00053762.PDF

6. Alberta Health, Government of Alberta. Alberta Public Health Disease Management Guidelines: Invasive Pneumococcal Disease. 2021; Available from: https://open.alberta.ca/dataset/67a2161b-d849-4fd4-8c02-9a1be7c65809/resource/9750e6df-ed5d-48b5-93b4-bd70a9b41b00/download/health-phdmg-pneumoccocal-disease-invasive-2021-09.pdf

i. APPENDIX A: Pneu-C20 Eligibility for Populations at Increased Risk of Invasive Pneumococcal Disease (IPD)

Does the individual have any of the following medical conditions?

- Asplenia/hyposplenism (functional or anatomic)
- Chronic renal disease, including nephrotic syndrome, on dialysis, or with renal transplant.
- 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.
- Immunosuppressive therapy including:
  - long-term use of corticosteroids,
  - chemotherapy (undergoing or anticipating),
  - radiation therapy (undergoing or anticipating),
  - post-organ transplant therapy,
  - biologic and non-biologic immunosuppressive therapies for:
    - inflammatory arthropathies, e.g., systemic lupus erythematosus (SLE), rheumatoid or juvenile arthritis,
    - inflammatory dermatological conditions, e.g., psoriasis, severe atopic dermatitis and eczema, and
    - inflammatory bowel disease, e.g., 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.

NOTE: Individuals 18 years of age and older who have received one dose of Pneu-C20 are considered complete, and do not need to be assessed through the algorithm.

Yes → 18 years of age or older?
- No → **Eligible** (at AHS only)
- Yes → Previously received 2 doses of Pneumo-P AND at least one dose of Pneu-C13 ?
  - Yes → Received one dose of Pneumo-P at 65 years of age or older?
    - Yes → **Not Eligible**
    - No → **Eligible at 65+**
  - No → **Eligible**

No

Does the individual meet any of the following criteria?

Is a member of populations with sustained high rates of IPD:
- First Nations, Métis, and Inuit peoples, regardless of where they live
- Resident of continuing care homes and senior supportive living accommodations

OR Has any of the medical conditions listed below:
- 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

OR Is an individual who:
- Has an alcohol use disorder
- Uses illicit drugs
- Smokes or vapes
- Has poor air quality in the home (including, but not limited to, second-hand smoke, wood fired stoves)
- Is experiencing houselessness

Yes → 18 years of age or older?
- No → **Eligible** (at AHS only)
- Yes → Previously received one dose of Pneumo-P?
  - Yes → Received one dose of Pneumo-P at 65 years of age or older?
    - Yes → **Not Eligible**
    - No → **Eligible at 65+**
  - No → **Eligible**

No → 65 years of age or older?
- Yes → Previously received a dose of Pneumo-P or Pneu-C20?
  - Yes → **Not Eligible**
  - No → **Eligible**
- No → **Not Eligible**

NOTE: For Solid Organ Transplant (SOT) or Hematopoietic Stem Cell Transplants (HSCT) recipients see: Child HSCT, Adult HSCT, Child SOT before 18 months of age, Child SOT after 18 months of age, or Adult SOT.

