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

Alberta Health Services
Communicable Disease Control

BIOLOGICAL PAGE

Section 7	Biological Product Information	**Standard # 07.293**	
Created and approved by	Provincial Immunization Program Standards and Quality		
Approval date	June 24, 2024	**Revised**	

	PREVNAR 20™ Pneumococcal 20-valent Conjugate Vaccine (Pneu-C20)
Manufacturer	Pfizer Canada Inc.
Biological Classification	Inactivated: Conjugate
Indications for 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 groups at increased risk for Invasive Pneumococcal Disease (IPD). • Individuals 18 years of age and older who belong to one or more of the groups at increased risk for IPD and did not receive the previously recommended doses of pneumococcal conjugate and polysaccharide vaccines. • To determine eligibility, please refer to the Pneu-C20 Eligibility for Populations at Increased Risk of Invasive Pneumococcal Disease (IPD) 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 individuals, including First Nations, regardless of where they live. *Individuals with the following medical conditions* (See Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression): • Asplenia/hyposplenism (functional or anatomic). • 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). • Chronic renal disease, including nephrotic syndrome, on dialysis or with renal transplant. • Cochlear implants (candidates and recipients). • 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. • Diabetes mellitus.

- 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,
  - post-organ transplant therapy,
  - biologic and non-biologic immunosuppressive therapies for, examples include:
    - 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; 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 one dose of Pneu-C20 are not eligible for another dose. Reimmunization using a same-valency conjugate 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.
- Previous IPD does not confer immunity or preclude immunization with pneumococcal conjugate vaccine. 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 Alberta public health disease management guidelines : pneumococcal disease, invasive (IPD).

	PREVNAR 20™ Pneumococcal 20-valent Conjugate Vaccine (Pneu-C20)
Serology	**N/A**
Schedule	**Children 6 weeks of age to 17 years of age at high-risk for IPD** Starting immunization at: 2 months up to and including 6 months of age (4 doses) • 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. Seven months up to and including 11 months of age (3 doses) • 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 12 months up to and including 24 months of age (2 doses) • Dose 1: day 0 • Dose 2: eight weeks after dose 1 25 months and older • 1 dose **Note:** • Dose 1 may be administered to infants as early as six weeks of age. • 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. • The reinforcing dose is to be given in the second year of life (12 months of age or older), and at least 8 weeks from previous dose. • The minimum interval between doses for children receiving immunization after 12 months of age is eight weeks. For children who have received HSCT and/or CAR T-cell therapy see - Immunization for Child HSCT Transplant Recipients For children who have received SOT see – Immunization for Children Expecting SOT Before 18 Months of Age or Immunization for Children Expecting SOT After 18 Months of Age **Notes**: • High-risk children who started a series with another pneumococcal conjugate vaccine, should complete their series with Pneu-C20. 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. • 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. 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 vaccine.

	PREVNAR 20™ Pneumococcal 20-valent Conjugate Vaccine (Pneu-C20)		
	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 59 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
	5 years of age and older		
	Any incomplete schedule	1 dose	

Adults 18 years of age and older at 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. 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, 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, examples include:
    - 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 one 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

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

Individuals 65 years of age and older who have not received a Pneumo-P vaccine dose on or after 65 years of age or a dose of Pneu-C20.

- 1 dose

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 Pneumo-P vaccine before receiving Pneu-C20.

	PREVNAR 20™ Pneumococcal 20-valent Conjugate Vaccine (Pneu-C20)
	Note: • If possible, vaccine should be administered at least 14 days before splenectomy or initiation of immunosuppressive therapy. • 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. • 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.
Preferred Use	N/A
Dose	0.5 mL
Route	Intramuscular injection
Contraindications/ Precautions	**Contraindications** • Known severe hypersensitivity to any component of Pneu-C20 including diphtheria toxoid. • 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.
Possible Reactions	**Common:** • Pain, redness, swelling at injection site • Irritability • Drowsiness/Increased sleep • Decreased appetite • Fever • Muscle pain • Fatigue • Headache • Joint pain • Chills • Vomiting • Diarrhea • Rash **Uncommon:** • Hypersensitivity reaction, including face edema, dyspnea, bronchospasm • Angioedema • Vaccination-site pruritus, lymphadenopathy, vaccination-site urticaria • Urticaria or urticaria like rash • Seizures **Rare:** • Anaphylaxis • Allergic reaction • Vaccination site hypersensitivity As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.

	PREVNAR 20™ Pneumococcal 20-valent Conjugate Vaccine (Pneu-C20)
Pregnancy	• Safety during pregnancy has not been established in humans. • 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.
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. 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.

Composition	Each 0.5 mL dose contains:
	• Active substances individually linked to the non-toxic diphtheria (CRM_{197}) carrier protein:
	  ○ 2.2 mcg of each of *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F and 33F
	  ○ 4.4 mcg of *S. pneumoniae* serotype 6B
	• Nonmedicinal ingredients:
	  ○ 125 mcg aluminum phosphate
	  ○ 100 mcg polysorbate 80
	  ○ 4.4 mcg sodium chloride
	  ○ 295 mcg succinic acid
	  ○ Water for injection

Blood/Blood Products	Does not contain any blood products.
Bovine/Porcine Products	Does not contain any bovine or porcine products.
Latex	No latex in the product.
Interchangeability	N/A
Administration with Other Products	Can be administered concomitantly with other inactivated and live vaccines using a separate needle and syringe for each vaccine. The same limb may be used, if necessary, but different sites on the limb must be used.
Appearance	A homogenous white suspension
Storage	• Store between 2°C and 8°C. • Store syringes horizontally in the fridge to minimize re-dispersion time. • Administer as soon as possible once removed from cold chain. • Do not freeze.
Vaccine Code	PNEU-C20
Antigen Code	PNEUMO-C
Licensed for	Individuals 6 weeks of age and older.
Notes	• 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 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.
Related Resources	Pneumococcal Conjugate (PNEU-C20) Vaccine Information Sheet (105626).

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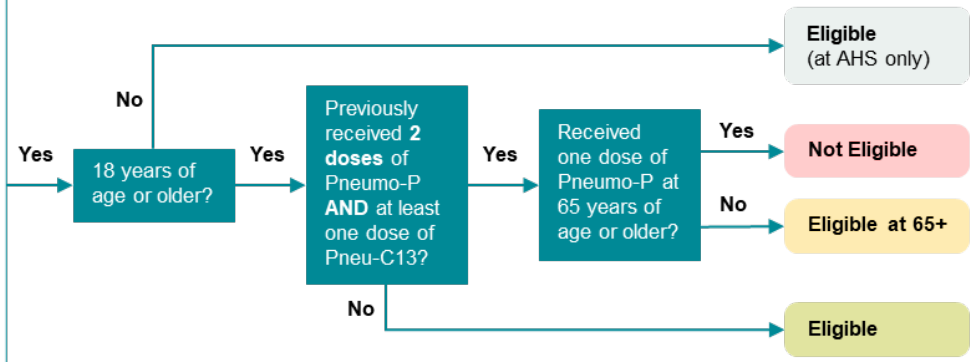
Appendix A

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.



No

Does the individual meet any of the following criteria?

Is a member of populations with sustained high rated of IPD:

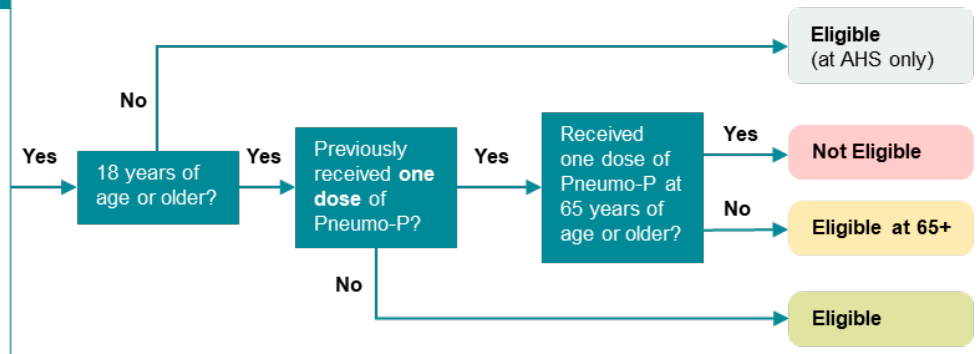
- First Nations, Métis, and Inuit peoples, regardless of where they live
- Resident of continuing care homes and senior supportive living accommodations

OR Has any of the following 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

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



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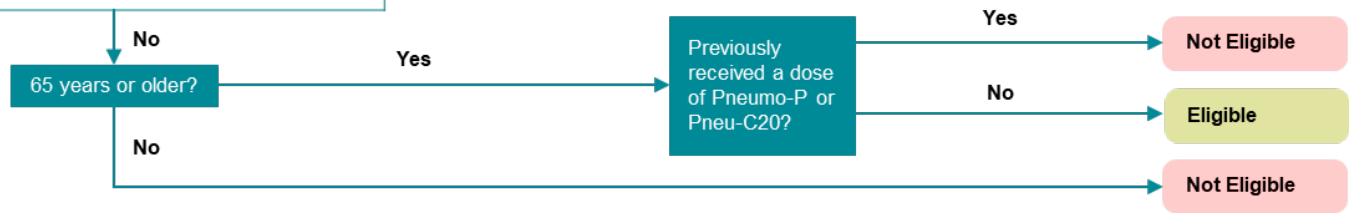

Note: For Solid Organ Transplant (SOT) or Hematopoietic Stem Cell Transplants (HSCT) recipients, see: Child HSCT, Adult HSCT, Child SOT before 18 months of age,