Alberta Health Services	**Pneumococcal 13-valent Conjugate Vaccine Biological Page**		
Section 7:	**Biological Product Information**		**Standard #: 07.291**
Created by:	Province-wide Immunization Program Standards and Quality		
Approved by:	Province-wide Immunization Program Standards and Quality		
Approval Date:	February 1, 2012	**Revised:**	June 1, 2023

	Prevnar® 13
Manufacturer	T.M. Wyeth, Pfizer Canada Inc.
Biological Classification	Inactivated
Indications for Provincially Funded Vaccine	**Healthy Children:** • 2 months up to and including 59 months of age. • Catch-up: children up to and including 59 months of age who have completed pneumococcal conjugate immunization with a conjugate vaccine other than Prevnar®13 should be offered a single dose of Prevnar® 13 vaccine if they present prior to their 5th birthday (preferably at their preschool immunization appointment). **High Risk Individuals:** • **2 months up to and including 17 years of age** ○ Asplenia/hyposplenism (functional or anatomic) See Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression #08.305. ○ Chronic cardiac disease. ○ Chronic cerebral spinal fluid (CSF) leak. ○ Chronic liver disease (including hepatitis B and C and hepatic cirrhosis due to any cause). ○ Chronic neurologic condition that may impair clearance of oral secretions. ○ Chronic pulmonary disease (excluding asthma unless treated with ○ High-dose oral corticosteroid therapy). ○ Chronic renal disease, including nephrotic syndrome. ○ 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) recipients See - Immunization for Child Hematopoietic Stem Cell Transplant Recipients. ○ HIV infection. ○ Immunosuppressive therapy including: ▪ use of long term corticosteroids, ▪ chemotherapy, ▪ radiation therapy, ▪ post-organ transplant therapy, ▪ biologic and non-biologic immunosuppressive therapies for: ▪ inflammatory arthropathies, e.g., systemic lupus erythematosus (SLE), rheumatoid or juvenile arthritis,

	Prevnar® 13
	▪ inflammatory dermatological conditions, e.g., psoriasis, severe atopic dermatitis and eczema, and ▪ inflammatory bowel disease, e.g., Crohn's disease, ulcerative colitis. For additional information see: See Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression #08.305. **Note:** Individuals prescribed eculizumab (Soliris®) are at increased risk of serious infections, especially with encapsulated bacteria, such as *Streptococcus pneumoniae;* therefore, they should receive Prevnar® 13 at least two weeks before receiving the first doses of Solaris® if possible. See the Pneumococcal Polysaccharide Vaccine # 07.290 and Pneumococcal Conjugate #07.291 Vaccine Biological Pages regarding scheduling for spacing between products. ○ Malignant hematologic disorders (affecting the bone marrow or lymphatic system) including leukemia, lymphoma, Hodgkin's disease and multiple myeloma. ○ Malignant solid organ tumors undergoing or anticipating immunosuppressive therapy (chemotherapy or radiation). ○ Sickle-cell disease and other hemoglobinopathies. ○ Solid organ or islet transplant (SOT) candidates and recipients. See Standard for Immunization of Transplant Candidates or Recipients #08.304. • **Adults 18 years of age and older with conditions resulting in high risk for IPD as listed below:** ○ Asplenia (anatomical or functional). ○ Chronic CSF leak. ○ 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. ○ HIV infection. ○ HSCT recipients. See Standard for Immunization of Transplant Candidates or Recipients #08.304. ○ Immunosuppressive therapy including use of long term corticosteroids, chemotherapy, radiation therapy, post-organ transplant therapy, biologic and non-biologic immunosuppressive therapies for rheumatologic and other inflammatory diseases. For additional information see: See Standard on the Immunization of Individuals with Chronic Health Conditions and/or Immunosuppression #08.305. **Note:** Individuals prescribed eculizumab (Soliris®) are at increased risk of serious infections, especially with encapsulated bacteria, such as *Streptococcus pneumoniae;* therefore, they should receive Prevnar® 13 at least two weeks before receiving the first dose of Soliris® if possible. See the Pneumococcal Polysaccharide Vaccine # 07.290 and Pneumococcal Conjugate #07.291 Vaccine Biological Pages regarding scheduling for spacing between products. ○ Malignant hematologic disorders (affecting the bone marrow or lymphatic system) including leukemia, lymphoma Hodgkin's disease and multiple myeloma. ○ Malignant solid organ tumors undergoing or anticipating immunosuppressive therapy (chemotherapy or radiation). ○ Nephrotic Syndrome.

<table>
<tr><th></th><th>Prevnar® 13</th></tr>
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Sickle cell disease and other hemoglobinopathies.
Solid organ or islet cell transplant candidates and recipients. See – Standard for Immunization of Transplant Candidates or Recipients #08.304.

Notes:

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.
Individuals 2 years of age and older at high risk may be eligible for both pneumococcal 13-valent conjugate vaccine and pneumococcal polysaccharide vaccine (see Pneumococcal Polysaccharide Vaccine Biological Page for indications)
Individuals 18 years of age and older, including those with conditions that place them at higher risk for IPD, who have received 20-valent pneumococcal conjugate vaccine (PCV 20) according to the schedule(s) outlined in the product monograph are not recommended to receive Pneu-C13 at this time.
Having received a dose of 20-valent pneumococcal conjugate vaccine (PCV 20) can be considered sufficient for individuals recommended Pneu-C13 or Pneu-C13 in combination with Pneumo-P23.

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<tr><td>Schedule</td><td>
General Schedule Considerations:

Healthy children routinely receive 3 doses scheduled at 2, 4 and 12 months of age
High risk individuals (see indications section for definition of high risk) routinely receive 4 doses scheduled at 2, 4, 6 and 12 months of age. The exception to this is SOT candidates and recipients and HSCT recipients. Refer to Standard for Immunization of Transplant Candidates and Recipients #08.304 for details regarding scheduling and spacing intervals between doses.

Healthy children who completed the routine schedule for healthy children (3 dose series) and subsequently become immunocompromised do not require any additional doses of pneumococcal conjugate vaccine. The additional dose for high risk infants is intended to protect them during the first year of life.

Indigenous children (defined as having at least one parent who is indigenous; includes First Nations, Inuit and Metis) beginning immunization at younger than 7 months should receive four doses of vaccine at 2, 4, 6 and 12 months similar to children under 7 months who are high risk.
Fewer doses of vaccine may be needed for individuals who are not immunized according to the routine immunization schedule.
The following pages contain detailed routine and interrupted schedule charts, including recommended spacing between doses, for healthy and high risk individuals.

Catch-up:

Children up to and including 59 months of age who have completed pneumococcal conjugate immunization with a conjugate vaccine other than Prevnar® 13 should be offered a single dose of Prevnar® 13 if they present prior to their 5th birthday (preferably at their preschool appointment)

The catch-up dose must be at least 8 weeks after the last dose of pneumococcal conjugate and at least 8 weeks after any dose of pneumococcal polysaccharide vaccine.

Routine Schedule for Healthy Children (3 dose series):
<table>
<tr><th>Starting immunization at:</th><th>Primary Series
(4 to 8 weeks apart)</th><th>Reinforcing Dose
(given in the second year of life at least 8 weeks after last dose)</th></tr>
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Prevnar® 13

2 months up to and including 11 months of age (3 doses)	2 doses Routinely given at the 2 and 4 month clinic visit.	1 dose Routinely given at the 12 month clinic visit.
12 months up to and including 23 months of age (2 doses)	1 dose	1 dose
24 months up to and including 59 months of age	1 dose	

Notes:

- For children who began immunization with a pneumococcal conjugate vaccine other than Prevnar® 13, immunization can be completed using Prevnar® 13. There is no need to restart the vaccine series.
- All children that have completed a vaccine series using a pneumococcal conjugate vaccine other than Prevnar® 13 should receive a single dose of Prevnar® 13 prior to their fifth birthday (preferably during their preschool immunization appointment).
- Minimum age to receive Prevnar® 13 is 6 weeks.
- The recommended interval between doses for children less than 1 year of age is 8 weeks. However, the interval can be shortened to 4 weeks if necessary.
- The minimum interval between doses for children receiving immunization after 12 months of age is 8 weeks.
- The third dose or reinforcing dose should be given at 12 months of age or older and at least eight weeks after previous dose.

Interrupted Schedule for Healthy Children (3 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 dose)
3 months up to and including 11 months at re-presentation		
0 previous doses	2 doses	1 dose
1 previous dose	1 dose	1 dose
2 previous doses	Primary series complete	1 dose
12 months up to and including 23 months at re-presentation		
0 to 1 previous dose prior to 12 months	1 dose	1 dose
2 previous doses prior to 12 months	Primary series complete	1 dose
1 previous dose at 12 months or later	Primary series complete	1 dose
24 months up to and including 59 months at re-presentation		
Any incomplete age appropriate schedule	1 dose	

Notes:

- The recommended interval between doses for children less than 1 year of age is 8 weeks. However, the interval can be shortened to 4 weeks if necessary.
- The minimum interval between doses for children receiving immunization after 12 months of age is 8 weeks.
- The reinforcing dose should be given at 12 months of age or older and at least eight weeks after the final dose of the primary series.

Routine Schedule for High Risk Individuals (4 dose series):

Prevnar® 13

Starting immunization at:	Primary Series (4 to 8 weeks apart)	Reinforcing Dose (given in the second year of life at least 8 weeks after previous dose)
2 months up to and including 6 months of age (4 doses)	3 doses Routinely given at the 2, 4 and 6 month clinic visit. (for delayed immunization schedules, the interval between the 2nd and 3rd dose may be shortened to four weeks).	1 dose Routinely given at the 12 month clinic visit.
7 months up to and including 11 months of age (3 doses)	2 doses	1 dose
12 months up to and including 59 months of age (2 doses)	1 dose	1 dose
5 years and older	1 dose	

Notes:

- For children who began immunization with a pneumococcal conjugate vaccine other than Prevnar® 13, immunization can be completed using Prevnar® 13. There is no need to restart the vaccine series.
- All children that have completed a vaccine series using a pneumococcal conjugate vaccine other than Prevnar® 13 should receive a single dose of Prevnar® 13 prior to their fifth birthday (preferably during their preschool immunization appointment).
- Children at **high risk** for IPD who have completed pneumococcal conjugate immunization with a conjugate vaccine other than PREVNAR® 13 should be offered a single dose of PREVNAR® 13 vaccine. The catch-up dose must be at least eight weeks after the last dose of pneumococcal conjugate vaccine and at least eight weeks after any dose of pneumococcal polysaccharide vaccine.
- Minimum age to receive Prevnar® 13 is 6 weeks.
- The recommended interval between doses for children less than 1 year of age is 8 weeks. However, the interval can be shortened to 4 weeks if necessary.
- The minimum interval between doses for children receiving immunization after 12 months of age is 8 weeks.
- If possible vaccine should be administered at least 14 days before splenectomy or initiation of immunosuppressive therapy.
- When both pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine are indicated, the pneumococcal conjugate vaccine should be administered first with a minimum interval of at least 8 weeks between the 2 vaccines. However if pneumococcal polysaccharide vaccine has already been administered, there must be an interval between doses as specified below:
  - Children 2 years up to and including 17 years of age: pneumococcal conjugate vaccine may be administered with a minimum interval of at least 8 weeks after the pneumococcal polysaccharide vaccine
  - Adults 18 years of age and older: pneumococcal conjugate vaccine may be administered with a minimum interval of at least 1 year after the pneumococcal polysaccharide vaccine.
  - **The exception to this is HSCT recipients.** Refer to Standard for Immunization of Transplant Candidates and Recipients #08.304.
- Adults at high risk for IPD who have completed pneumococcal conjugate immunization with a conjugate vaccine other than PREVNAR® 13 should be considered complete (no further doses of pneumococcal conjugate vaccine are required).

Prevnar® 13

Interrupted Schedule for High Risk Individuals (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 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 dose 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 or later	Primary series complete	1 dose
5 years of age and older		
Any incomplete age appropriate schedule	1 dose	

Notes:

- For children who began immunization with a pneumococcal conjugate vaccine other than Prevnar® 13, immunization can be completed using Prevnar® 13. There is no need to restart the vaccine series.
- All children that have completed a vaccine series using a pneumococcal conjugate vaccine other than Prevnar® 13 should receive a single dose of Prevnar® 13 prior to their fifth birthday (preferably during their preschool immunization appointment).
- Children at **high risk** for IPD who have completed pneumococcal conjugate immunization with a conjugate vaccine other than PREVNAR® 13 should be offered a single dose of PREVNAR® 13 vaccine. The catch-up dose must be at least eight weeks after the last dose of pneumococcal conjugate vaccine and at least eight weeks after any dose of pneumococcal polysaccharide vaccine.
- Minimum age to receive Prevnar® 13 is 6 weeks.
- The recommended interval between doses for children less than 1 year of age is 8 weeks. However, the interval can be shortened to 4 weeks if necessary. The third dose or reinforcing dose should be given at 12 months of age or older.
- The minimum interval between doses for children receiving immunization after 12 months of age is 8 weeks.
- 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 hematologic disorders currently undergoing immunosuppressive therapy the vaccine should be administered as soon as possible.
- Individuals 2 years of age and older at high risk may be eligible for both pneumococcal 13-valent conjugate vaccine and pneumococcal polysaccharide vaccine (see Pneumococcal Polysaccharide Vaccine Biological Page for indications).

	Prevnar® 13
	• When both pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine are indicated, the pneumococcal conjugate vaccine should be administered first with a minimum interval of at least 8 weeks between the 2 vaccines. However if pneumococcal polysaccharide vaccine has already been administered, there must be an interval between doses as specified below: ○ Children 2 years up to and including 17 years of age: pneumococcal conjugate vaccine may be administered with a minimum interval of at least 8 weeks after the pneumococcal polysaccharide vaccine ○ Adults 18 years of age and older: pneumococcal conjugate vaccine may be administered with a minimum interval of at least 1 year after the pneumococcal polysaccharide vaccine. ○ **The exception to this is HSCT recipients.** Refer to Standard for Immunization of Transplant Candidates and Recipients #08.304. • Adults at high risk for IPD who have completed pneumococcal conjugate immunization with a conjugate vaccine other than PREVNAR® 13 should be considered complete (no further doses of pneumococcal conjugate vaccine are required)**.**
Preferred Use	N/A
Dose	0.5 mL
Route	IM
Contraindications/ Precautions	This vaccine **should not** be given to individuals who: • have had an anaphylactic reaction to a previous dose of this vaccine • have a known hypersensitivity to any component of the vaccine • present with a serious acute febrile illness: ○ Recommendations should be provided for these individuals to be immunized when their symptoms have resolved. ○ Individuals with non-serious febrile illness may be immunized. • Will not protect against s pneumonia serotypes not included in the vaccine. • Will not protect against other microorganisms that cause invasive disease, pneumonia or otitis media. • Does not replace the use of Pneumovax 23 in high risk children 24 months of age and older.

	Prevnar® 13
Possible Reactions	**Common:** • injection site pain, redness, warmth, swelling and local induration • fever (greater than 39°C) • chills • decreased appetite • irritability • drowsiness/increased sleep or restless sleep/decreased sleep • headache • muscle pain, joint pain • diarrhea and vomiting • rash **Rare:** • seizure (including febrile seizures) • crying • urticaria or urticaria like rash • hypersensitivity reaction including facial edema, dyspnea and bronchospasm • hypotonic-hyporesponsive episode • lymphadenopathy localized to the region of the injection site • anaphylaxis • angioedema; erythema multiforme • vaccine site dermatitis, pruritus • As with any immunization, unexpected or unusual side effects can occur. Refer to the product monograph for more detailed information.
Pregnancy	Can be administered to eligible pregnant women.
Lactation	Can be administered to eligible breastfeeding women.
Composition	Each 0.5 mL dose contains: • 2.2 mcg each of saccharide for *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F and 23F • 4.4 mcg saccharide for *Streptococcus pneumoniae* serotype 6B • non-toxic diphtheria CRM 197 carrier protein • aluminum phosphate • sodium chloride • succinic acid • polysorbate 80 • sterile water for injection
Blood/Blood Products	Contains no human blood or blood products.
Bovine/Porcine Products	Contains no bovine or porcine products. Casamino acids are used in the manufacturing process.
Latex	There is no latex in the vaccine or the vaccine packaging.
Interchangeability	Children who have started their immunization schedule with a different pneumococcal conjugate vaccine may complete the series using Prevnar® 13 vaccine. There is no need to restart the immunization series.

	Prevnar® 13
Administration with Other Products	• When both pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine are indicated, the pneumococcal conjugate vaccine should be administered first with a minimum interval of at least 8 weeks between the 2 vaccines. However if pneumococcal polysaccharide vaccine has already been administered, there must be an interval between doses as specified below: ○ Children 2 years up to and including 17 years of age: pneumococcal conjugate vaccine may be administered with a minimum interval of at least 8 weeks after the pneumococcal polysaccharide vaccine ○ Adults 18 years of age and older: pneumococcal conjugate vaccine may be administered with a minimum interval of at least 1 year after the pneumococcal polysaccharide vaccine. ○ **The exception to this is HSCT recipients.** Refer to Standard for Immunization of Transplant Candidates and Recipients #08.304. • Prevnar® 13 vaccine can be given at the same time as other inactivated and live vaccine 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 chosen.
Appearance	White suspension; the vaccine should be shaken well to obtain a homogeneous solution.
Storage:	• Store at $+2^0$C to $+8^0$C. • Do not freeze. • Do not use beyond the labeled expiry date. • Store in original packaging when possible to protect from light.
Vaccine Code	PNEU-C13
Antigen Code	PNEUMO-C
Licensed for	• Individuals 6 weeks and older

Notes:

- Prevnar® 13 vaccine eligibility criteria was expanded to include more high risk categories and eligibility criteria was changed to 2 months up to and including 59 months(September 2014).
- Prevnar® 13 vaccine eligibility was expanded to include HIV infected individuals 6 years of age and older beginning February 1, 2012.
- Prevnar® 13 vaccine replaced the Prevnar® vaccine in the routine childhood immunization schedule on July 1, 2010. A catch-up program for children who had completed a pneumococcal conjugate series using Prevnar® vaccine was included in this program change.
- The routine immunization schedule in Alberta changed from a 4 dose to a 3 dose schedule for healthy children on July 1, 2010. High risk children continue to receive 4 doses.
- Prevnar® was introduced into the routine childhood immunization schedule in Alberta on September 1, 2002. The vaccine was offered at the 2, 4, 6 and 18 month immunization appointments.

Related Documents:

- Pneumococcal Conjugate Vaccine Information Sheet (104502) (November 2020)

	Prevnar® 13

References:

1. Alberta Health, Public Health and Compliance Division Alberta Immunization Policy (2018 March 15). Pneumococcal Vaccines: Prevnar® 13
2. Alberta Health (2014). Adverse Events Following Immunization (AEFI), Policy for Alberta Health Services Public Health. National Advisory Committee on Immunization. (2012). *Canadian Immunization Guide (Evergreen Edition).* Ottawa, ON: Public Health Agency of Canada. http://www.phac-aspc.gc.ca/publicat/cig-gci/
3. National Advisory Committee on Immunization (2023 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. 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
4. National Advisory Committee on Immunization. (2010). Update on the use of conjugate pneumococcal vaccines in childhood. *Canadian Communicable Disease Report,* 36 (ACS-12). http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/10vol36/acs-12/index-eng.php
5. T.M. Wyeth, Pfizer Canada Inc. (September 17, 2015). Prevnar® 13: Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM 197 Protein). *Product monograph.*