Pneumococcal Vaccine, 13-valent Conjugate: Prevnar® 13

Revision Date: March 15, 2018

Rationale for Update:

- Clarifying eligibility for individuals with malignant solid organ tumors and long term immunosuppression.

Please consult the Product Monograph[1] for further information about the product.	
	PREVNAR® 13
Manufacturer	T.M. Wyeth, Pfizer Canada Inc.
Licensed use	Individuals 6 weeks of age and older
Off-license use	None
Indications for use of provincially funded vaccine	• **All children two months up to and including 59 months of age.** • **Children five years up to and including 17 years of age with conditions resulting in high risk for invasive pneumococcal disease (IPD) as listed below:** ➢ Asplenia/hyposplenism (functional or anatomic)[2] See Special Situations for Immunization – Immunization of Specific Populations ➢ Chronic cardiac disease.[2] ➢ Chronic cerebral spinal fluid (CSF) leak.[2] ➢ Chronic liver disease (including hepatitis B and C and hepatic cirrhosis due to any cause).[2] ➢ Chronic neurologic condition that may impair clearance of oral secretions.[2] ➢ Chronic pulmonary disease[2] (excluding asthma unless treated with high-dose oral corticosteroid therapy). ➢ Chronic renal disease, including nephrotic syndrome.[2] ➢ Cochlear implants (candidates and recipients).[2] ➢ 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 funtions.[2] ➢ Diabetes mellitus[2] ➢ Hematopoietic stem cell transplant (HSCT) recipients.[2] See - Immunization for Child Hematopoietic Stem Cell Transplant Recipients. ➢ HIV infection.[2] ➢ Immunosuppressive therapy including: [2,4] o use of long term corticosteroids, o chemotherapy, o radiation therapy, o post-organ transplant therapy, o 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®) are at increased risk of serious infections, especially with encapsulated bacteria, such as *Streptococcus pneumoniae;*[3] therefore, they should receive Prevnar® 13 at least two weeks before receiving the first doses of Solaris® if possible. See scheduling for spacing between Prevnar® 13 and Pneumovax® 23. For additional information see: Immunization of Specific Populations ➢ Malignant hematologic disorders (affecting the bone marrow or lymphatic system) including leukemia, lymphoma,[2] Hodgkin's disease and multiple myeloma. [2] ➢ Malignant solid organ tumors undergoing or anticipating immunosuppressive therapy (chemotherapy or radiation).[2] ➢ Sickle-cell disease and other hemoglobinopathies.[2] ➢ Solid organ or islet transplant (SOT) candidates and recipients.[2] See 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). • **Adults 18 years of age and older with conditions resulting in high risk for IPD as listed below:** ➢ Asplenia (anatomical or functional). [2,4] ➢ Chronic CSF leak.[5] ➢ Cochlear implants (candidates and recipients).[5] ➢ 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.[4] ➢ HIV infection.[4] ➢ HSCT recipients.[4] See Immunization for Adult Hematopoietic Stem Cell Transplant Recipients. ➢ 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.[4] **Note**: Individuals prescribed eculizumab (Soliris®) are at increased risk of serious infections, especially with encapsulated bacteria, such as *Streptococcus pneumoniae;*[3] therefore, they should receive Prevnar® 13 at least two weeks before receiving the first dose of Soliris® if possible. See scheduling for spacing between Prevnar® 13 and Pneumovax® 23. 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 undergoing or anticipating immunosuppressive therapy (chemotherapy or radiation).[2] ➢ Nephrotic Syndrome. [2] ➢ Sickle cell disease and other hemoglobinopathies. [2,4] ➢ Solid organ or islet cell transplant candidates and recipients. [2,4] See - Immunization for Adult Solid Organ Transplant Candidates and Recipients.

<table>
<tr><td></td><td colspan="3">Post-exposure
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 Public Health Notifiable Disease Management Guidelines – Invasive Pneumococcal Disease[6]</td></tr>
<tr><td>Dose</td><td colspan="3">0.5 mL</td></tr>
<tr><td>Route</td><td colspan="3">Intramuscular injection</td></tr>
<tr><td rowspan="11">Schedule</td><td colspan="3">Prevnar® scheduling for high-risk children younger than two years of age differs from the routine schedule for healthy children of the same age. See schedules below.</td></tr>
<tr><td colspan="3">Healthy Children – Routine Schedule</td></tr>
<tr><td colspan="3">Starting immunization at:</td></tr>
<tr><td>2 months up to and including 11 months of age (3 doses)</td><td colspan="2">❖ Dose 1: two months of age
❖ Dose 2: four months of age
❖ Dose 3: 12 months of age.</td></tr>
<tr><td>12 months up to and including 23 months of age (2 doses)</td><td colspan="2">❖ Dose 1: primary dose - day 0
❖ Dose 2: reinforcing dose - eight weeks after 1st dose</td></tr>
<tr><td>24 months up to and including 59 months of age</td><td colspan="2">❖ One dose</td></tr>
<tr><td colspan="3">• Dose 1 may be administered to infants as early as six weeks of age.[1]
• The recommended interval between doses for children younger than one year of age is eight weeks. However, the interval may be shortened to four weeks.
• The third dose or reinforcing dose should be given in the second year of life (12 months of age or after).
• The minimum interval between doses for children receiving immunization after 12 months of age is eight weeks.</td></tr>
<tr><td colspan="3">Healthy Children – Catch-up Schedule</td></tr>
<tr><td>Number of Previous Doses</td><td>Completion of Primary Series</td><td>Reinforcing Dose (at least eight weeks after previous dose)</td></tr>
<tr><td colspan="3">3 months up to and including 11 months at re-presentation</td></tr>
<tr><td>0 previous doses</td><td>2 doses</td><td>1 dose</td></tr>
<tr><td>1 previous dose</td><td>1 dose</td><td>1 dose</td></tr>
<tr><td>2 previous doses</td><td>Primary series complete.</td><td>1 dose</td></tr>
<tr><td colspan="3">12 months up to and including 23 months at re-presentation</td></tr>
<tr><td>0 to 1 previous dose prior to 12 months</td><td>1 dose</td><td>1 dose</td></tr>
<tr><td>2 previous doses prior to 12 months</td><td>Primary series complete.</td><td>1 dose</td></tr>
<tr><td>1 previous dose after 12 months</td><td>Primary series complete</td><td>1 dose</td></tr>
</table>

	24 months up to and including 5 years of age		
	Any incomplete age-appropriate schedule	1 dose	
	• The recommended interval between doses for children younger than one year of age is eight weeks. However, the interval may be shortened to four weeks. • The reinforcing dose should be given in the second year of life (12 months of age or after) at least eight weeks after the final dose of the primary series. • The minimum interval between doses for children receiving immunization after 12 months of age is eight weeks.		
	High Risk Children – Routine Schedule		
	Starting immunization at:		
	Two months up to and including six months of age (4 doses)	❖ Dose 1: two months of age ❖ Dose 2: four months of age ❖ Dose 3: six months of age (for delayed immunization schedules the interval between the 2nd and 3rd dose may be shortened to four weeks). ❖ Dose 4: 12 months of age and a minimum of eight 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: 12 months of age and a minimum of eight weeks after the previous dose.	
	12 months up to and including 59 months of age (2 doses)	❖ Dose 1: day 0 ❖ Dose 2: eight weeks after 1st dose	
	5 years of age and older	❖ One dose	
	• Dose 1 may be administered to infants as early as six weeks of age.[1] • The recommended interval between doses for children younger than one year of age is eight weeks. However, the interval may be shortened to four weeks. • The third dose or reinforcing dose should be given in the second year of life (12 months of age or after). • The minimum interval between doses for children receiving immunization after 12 months of age is eight weeks.		
	High Risk Individuals – Catch-up Schedule		
	Number of Previous Doses	**Completion of Primary Series**	**Reinforcing Dose** *(At least eight weeks after previous dose)*
	3 months up to and including 6 months of age 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 of age		
	0 previous doses	2 doses	1 dose
	1 – 2 previous doses prior to 7 months	1 dose	1 dose
	12 months up to and including 59 months of age		
	0 to 1 previous doses prior to 12 months	1 dose	1 dose
	2 – 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	

- The recommended interval between doses for children younger than one year of age is eight weeks. However, the interval may be shortened to four weeks.
- The third dose or reinforcing dose should be given in the second year of life (12 months of age or after).
- The minimum interval between doses for children receiving immunization after 12 months of age is eight weeks.

Notes:

- Indigenous children (defined as having at least one parent who is aboriginal includes First Nations, Inuit and Metis) beginning immunization at younger than seven months of age should receive four doses of vaccine at 2, 4, 6 and 12 months of age as for children younger than seven months of age at high risk.
- 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.[9]
- Hematopoietic stem cell transplant (HSCT) recipients regardless of previous immunization status should receive three doses. See Immunization for Child Hematopoietic Stem Cell Transplant Recipients and Immunization for Adult Hematopoietic Stem Cell Transplant Recipients.
- If possible, vaccine should be administered at least 14 days before splenectomy or initiation of immunosuppressive therapy. [2]
- 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.[2]
- 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.[2]
- Individuals two years of age and older at high risk should receive pneumococcal polysaccharide vaccine as well.[2]

	• When both pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine are indicated **for children**, the pneumococcal conjugate vaccine should be administered first with a minimum interval of at least eight weeks between the two vaccines.[2] However, if pneumococcal polysaccharide vaccine has already been administered, there must be an interval of at least eight weeks before pneumococcal conjugate vaccine may be administered.[7,8] ➢ 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.[7,8] • When both pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine are indicated **for adults**, the pneumococcal conjugate vaccine should be administered first with a minimum interval of at least eight weeks between the two vaccines.[2] However, if pneumococcal polysaccharide vaccine has already been administered, there must be an interval of at least one year before pneumococcal conjugate vaccine may be administered.[4,10]
Contraindications	• Known severe hypersensitivity to any component of Prevnar® 13, including diphtheria toxoid. • Anaphylaxis to a previous dose of vaccine containing pneumococcal antigen.
Precautions	• Prevnar® 13 will not protect against *S. pneumoniae* serotypes not included in the vaccine. It will not protect against other micro-organisms that cause invasive disease, pneumonia or otitis media.[1] • Does not replace the use of Pneumovax® 23 in high-risk children 24 months of age and older.[1]
Possible reactions	See Product Monograph
Pregnancy	Pregnant women at high risk of IPD due to chronic medical conditions should receive pneumococcal conjugate vaccine if indicated. There is no evidence to suggest a risk to the fetus or to the pregnancy from maternal immunization with inactivated vaccines.[2]
Lactation	Breastfeeding women should receive pneumococcal conjugate vaccine[2] as indicated-if at high risk due to chronic medical conditions.
Program Notes	• 2002 September 1- 2010 June 30 – Prevnar® Pneumococcal Conjugate (7 valent)- Introduced into routine infant program (4 dose schedule given at 2, 4, 6 and 18 months of age) • 2010 July 1 – Prevnar®13 replaced 7 valent vaccine for infant program (3 dose schedule given at 2, 4, and 12 months of age for health children. High risk children continue to receive 4 doses). A catch-up program for children who had completed a pneumococcal conjugate series using Prevnar® vaccine was included in this program change • 2012 February 1 - Eligibility expanded to include HIV infected individuals 6 years of age and older. • 2014 October – Expanded indications for high-risk populations 5 to17 years of age including: 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, diabetes mellitus (poorly controlled), immunosuppressive therapy and malignant neoplasms (leukemia and lymphoma). - Expanded indications for high-risk adult populations added including: asplenia (anatomical or functional), chronic CSF leak, cochlear implants (candidates and recipients), congenital immunodeficiencies, immunosuppressive therapy, malignant neoplasms (including leukemia and lymphoma), sickle cell disease and other hemoglobinopathies. • 2015 February 10 – Expanded indication for immunosuppressive therapy regarding medication Solaris® • 2018 August – Clarified eligibility for individuals with malignant solid organ tumor and long term immunosuppression.

References

[1] T. M. Wyeth, Pfizer Canada Inc. (2015, September 17). Prevnar® 13: Pneumococcal 13-valent conjugate vaccine (diphtheria CRM197 protein). *Product Monograph*.

[2] National Advisory Committee on Immunization. (2017). *Canadian Immunization Guide* (Evergreen ed.). Ottawa, ON: Public Health Agency of Canada. www.canada.ca/en/public-health/services/canadian-immunization-guide.html

[3] Alexion Pharma International Sàrl.(2016, July 25). SOLIRIS® (eculizumab). *Product Monograph.*

[4] National Advisory Committee on Immunization. (2013, October). Statement on the use of conjugate pneumococcal vaccine – 13 valent in adults (Pneu-C-13). *Canada Communicable Disease Report 39 (ACS-5).*

[5] *Alberta Advisory Committee on Immunization. (2013, October 30). Record of Decisions (unpublished).*

[6] Alberta Health and Wellness. *Public Health Notifiable Disease Management Guidelines - Pneumococcal Disease, Invasive (IPD).* www.health.alberta.ca/professionals/notifiable-diseases-guide.html

[7] Centers for Disease Control and Prevention. (2013, June 28). Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine among Children Aged 6 – 18 Years with Immunocompromising Conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *Morbidity and Mortality Weekly Report, 62(25)*. Retrieved July 12, 2013 from, www.cdc.gov/mmwr/preview/mmwrhtml/mm6225a3.htm

[8] Immunization Action Coalition. (2017 December 15). Ask the Experts. Retrieved December 22, 2017 from, http://www.immunize.org/askexperts/experts_pneumococcal_vaccines.asp

[9] Expert opinion of pediatric infectious disease physicans (22 Sept 2017).

[10] Centers for Disease Control and Prevention. (2012, October). Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine for adults with immunocompromising conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *Morbidity and Mortality Weekly Report 61(40).* Retrieved June 7, 2013 from, www.cdc.gov/mmwr/preview/mmwrhtml/mm6140a4.htm

