New VFC Vaccine Available
Vaxneuvance (PCV15)

Vaxneuvance (15-valent pneumococcal conjugate vaccine, PCV15, CVX code: **215**, CPT code: **90671**) is now available through the Vaccines for Children (VFC) program. This advisory includes an overview of important information about Vaxneuvance.

Vaxneuvance is a vaccine indicated for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in individuals 2 months of age and older.

In 2021, Vanxneuvance was licensed by the Food and Drug Administration. On June 22, 2022, the Advisory Committee on Immunization Practices recommended use of PCV15 as an option for pneumococcal conjugate vaccination of persons aged <19 years, according to currently recommended 13-valent pneumococcal conjugate vaccine (PCV13) dosing and schedules. Risk-based recommendations on use of PPSV23 have not changed. **PCV15 as an option for pneumococcal conjugate vaccination is expected to reduce pneumococcal disease incidence in children because it induces immunity against additional disease-causing serotypes.**

VFC Supplies of Vaxneuvance (PCV15)
VFC supplies of Vaxneuvance may be given to VFC-eligible individuals according to currently recommended PCV13 dosing and schedules. ACIP recommends use of pneumococcal conjugate vaccine (PCV), either PCV13 or PCV15, for all children aged 2–59 months. In addition, risk-based PCV use is recommended for children aged 60–71 months with risk conditions, and persons aged 6–18 years with an immunocompromising condition, cerebrospinal fluid leak, or cochlear implant. For all recommendations, PCV13 and PCV15 can be used interchangeably. Interruption of the vaccination schedule does not require reinstitution of the entire series or the addition of extra doses.

Clinical Guidance

Dosing schedule
Administer Vaxneuvance as a 4-dose series at 2, 4, 6 and 12 through 15 months of age.

Coadministration with other vaccines
Concurrent PCV15 administration with vaccines containing diphtheria; tetanus; acellular pertussis; inactivated poliovirus; Haemophilus influenzae type b; hepatitis A; hepatitis B; measles, mumps, and rubella; rotavirus; and varicella were studied. Immunogenicity of these antigens was similar when administered concurrently with PCV15 and PCV13. Coadministration of PCV15 with meningococcal vaccines has not been studied. The same precautions used for coadministration of PCV13 and meningococcal vaccines should be applied when PCV15 is used. Risk for febrile seizures in children who received PCV15 concurrently with an influenza vaccine has not been studied. CDC and ACIP will continue to assess safety of PCV15; monitor the impact of implementation of new recommendations, including the impact on health equity; and assess postimplementation vaccine effectiveness. CDC and ACIP will update pneumococcal vaccination recommendations as appropriate.

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Recommended Administration Schedules

Table 1: Recommended schedule for use of pneumococcal conjugate vaccine* among previously unvaccinated infants, children, and adolescents, by age at first vaccination and health status

Age at first vaccination	Primary PCV13/PCV15 series*,†	PCV13/PCV15 booster dose*,§
All Children		
2–6 mos	3 doses	1 dose at 12–15 mos
7–11 mos	2 doses	1 dose at 12–15 mos
12–23 mos	2 doses	Not indicated
Healthy children		
24–59 mos	1 dose	Not indicated
Children with certain underlying medical conditions¶		
24–71 mos	2 doses	Not indicated
Children and adolescents with an immunocompromising condition,¶ cerebrospinal fluid leak, or cochlear implant		
6–18 yrs	1 dose	Not indicated

** Either PCV13 or PCV15 can be used to complete the recommended PCV series.*

† Minimum interval between doses is 8 weeks except for children vaccinated at age <12 months, for whom the minimum interval between doses is 4 weeks. The minimum age for administration of first dose is 6 weeks.

§ Administered ≥8 weeks after the previous PCV13/PCV15 dose.

¶ Certain underlying medical conditions include cerebrospinal fluid leak; chronic heart disease; chronic lung disease; cochlear implant; diabetes mellitus; immunocompromising conditions (chronic renal failure or nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; and sickle cell disease and other hemoglobinopathies). These children are also recommended to receive 23-valent pneumococcal polysaccharide vaccine.

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Table 2: Recommendations for administering pneumococcal conjugate vaccine* to incompletely vaccinated children, by age at visit, health status, and vaccination history

Age at visit	No. of previous PCV13/PCV15 doses received	Recommended PCV13/PCV15 regimen†	No. of PCV13/ PCV15 doses to complete series by age 24 mos
All Children			
2–6 mos	1	3 additional doses: 2 doses, 8 wks apart; last dose at age 12–15 mos	4
	2	2 additional doses: 1 dose, 8 wks after most recent dose; last dose at age 12–15 mos	4
	3	1 additional dose at age 12–15 mos	4
7–11 mos	1 or 2 (at age <7 mos) or 1 (at age ≥7 mos)	2 additional doses: 1 dose, 8 wks after last dose; last dose ≥8 wks later, at age 12–15 mos	3 or 4
	3 (at age <7 mos) or 2 (at age ≥7 mos)	2 additional doses: 1 dose, 8 wks after most recent dose; last dose at age 12–15 mos	3 or 4
12–23 mos	1 (at age <12 mos)	2 additional doses, ≥8 wks apart	3
	1 (at age ≥12 mos)	1 additional dose, ≥8 wks after most recent dose†	2
	2 or 3 (at age <12 mos)	1 additional dose, ≥8 wks after most recent dose	3 or 4
Healthy children			
24–59 mos	Any incomplete schedule by 24 mos	1 additional dose, ≥8 wks after most recent dose	NA
5–18 yrs	Any incomplete schedule by 24 mos	No additional dose	NA
All Children			
24-71 mos	Any incomplete schedule¶ of<3 doses by age 24 mos	2 doses: first dose ≥8 wks after most recent dose; second dose ≥8 wks later	NA
	3 (all at age <12 mos)	1 dose, ≥8 wks after most recent dose	NA

** Either PCV13 or PCV15 can be used to complete the recommended PCV series.*
† Minimum interval between doses is 8 weeks except for children vaccinated at age <1 year, for whom minimum interval between doses is 4 weeks.
§ Certain underlying medical conditions include cerebrospinal fluid leak; chronic heart disease; chronic lung disease; cochlear implant; diabetes mellitus; immunocompromising conditions (chronic renal failure or nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; and sickle cell disease and other hemoglobinopathies). These children are also recommended to receive 23-valent pneumococcal polysaccharide vaccine.
¶ See column "No. of PCV13/ PCV15 doses to complete series by age 24 mos" to determine an incomplete schedule of <3 doses by 24 months.

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Table 3. Risk-based pneumococcal vaccine recommendations for children and adolescents with underlying medical conditions that increase the risk for pneumococcal disease

Risk group/Condition	PCV* for children aged <6 yrs	PCV* for persons aged 6–18 yrs	PPSV23 for children aged ≥2 yrs	
	Recommended	Recommended	Recommended	Single revaccination 5 yrs after first dose
Immunocompetent children				
Chronic heart disease†	Yes	No	Yes	No
Chronic lung disease§	Yes	No	Yes	No
Diabetes mellitus	Yes	No	Yes	No
Cerebrospinal fluid leak	Yes	Yes	Yes	No
Cochlear implant	Yes	Yes	Yes	No
Healthy children				
Chronic renal failure or nephrotic syndrome	Yes	Yes	Yes	Yes
Congenital or acquired asplenia, or splenic dysfunction	Yes	Yes	Yes	Yes
Congenital or acquired immunodeficiency¶	Yes	Yes	Yes	Yes
Diseases and conditions treated with immunosuppressive drugs or radiation therapy**	Yes	Yes	Yes	Yes
HIV infection	Yes	Yes	Yes	Yes
Sickle cell disease or other hemoglobinopathies	Yes	Yes	Yes	Yes
Solid organ transplant	Yes	Yes	Yes	Yes

** Either PCV13 or PCV15 can be used.*
† Recommendations are of particular importance for children with cyanotic congenital heart disease and cardiac failure.
§ Including asthma if treated with high-dose oral corticosteroid therapy.
¶ Includes B-(humoral) or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, and C4 deficiency; and phagocytic disorders (excluding chronic granulomatous disease).
*** Including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease.*

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Storage

Vaxneuvance should be stored at 2° to 8°C (36° to 46°F). **Do not freeze.** Product which has been exposed to freezing should not be used. Do not use after the expiration date shown on the label.

How Vaxneuvance is supplied

Vaxneuvance is supplied as single-dose pre-filled syringes in packages of 10 doses (Vaxneuvance, NDC no. 00006-4329-03). The dosage for Vaxneuvance is 0.5 mL. Vaxneuvance does not contain a preservative. The vial stopper, syringe plunger stopper, and syringe tip cap are not made with natural rubber latex.

Administration

Just before use, shake the syringe until a uniform, white, cloudy suspension results. Inspect the syringe for particulate matter and discoloration prior to administration. If either of these conditions exist, the product should not be administered.

Administer a single 0.5 mL dose of Vaxneuvance intramuscularly.

Ordering and Billing

Vaxneuvance will be available for ordering through the PhilaVax IIS as of, Tuesday, January 3, 2022.

VFC sites must decide whether they will order PCV13 or PCV15 going forward. Scan the QR code, or use this link, to complete a survey to notify our program your site preference. We will review each site's submission and reach out with next steps. We recommend that sites that are part of a system or are affiliated use the same vaccine presentations across sites to ensure continuity of care and help prevent administration errors.

TAKE OUR SURVEY!

Resources

MMWR

https://www.cdc.gov/mmwr/volumes/71/wr/mm7137a3.htm

Vaxneuvance package insert

https://www.fda.gov/media/150819/download

What You Need to Know

https://www.immunize.org/vis/pcv.pdf

Vaccine Information Statement (VIS)

https://www.immunize.org/askexperts/

Immunize.org

www.immunize.org/askexperts/experts_pneumococcal_vaccines.asp#rec_child

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