

**Protocol for Pneumococcal Vaccines
PCV20 (Pevnar 20®), PCV15 (VAXNEUVANCE™), PCV13 (Pevnar 13®) and
Pneumococcal Polysaccharide Vaccine: PPSV23 (Pneumovax®23)**

1. What's New

A. N/A

2. Immunization Protocol

- A. Administer a 0.5-mL dose, IM, of pneumococcal conjugate vaccine (PCV) to persons ≥7 years of age according to age-appropriate schedule or high-risk group indication **OR**
- B. Administer a 0.5-mL dose, IM or SQ, of pneumococcal polysaccharide vaccine (PPSV) to persons ≥7 years of age according to age-appropriate schedule or high-risk group indication.
- C. PCV and PPSV should not be given at the same time. Either vaccine type may be given simultaneously with influenza and most other ACIP-recommended child and adult vaccinations.⁵

3. Vaccine Schedule

Pneumococcal Vaccine (PCV13 or PCV15, PPSV23) for Persons 7-18 Years of Age with Underlying Conditions* Dose-0.5-mL, Route varies by product				
Acceptable Age Range	Previous PCV13 Vaccination History	Previous PPSV23 Vaccination History	Due Now/Route (≥ 8 weeks since last pneumococcal vaccine)	Due Next
7-18 years of age with high-risk conditions	Unvaccinated	Unvaccinated	PCV13 or PCV15 IM	PPSV23 in ≥8 weeks. Revaccinate with PPSV23 in 5 years.
		1 dose	PCV13 or PCV15 IM	Revaccinate with PPSV23 in 5 years.
	≥1 dose of PCV13	Unvaccinated	PPSV23 IM or SQ	Revaccinate with PPSV23 in 5 years.
		1 dose	Complete	

*CSF leak, cochlear implant, sickle cell disease and other hemoglobinopathies, asplenia, HIV infection, chronic renal failure, nephrotic syndrome, immunodeficiency, diseases treated with immunosuppressive therapy or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; generalized malignancy; solid organ transplantation; or multiple myeloma. Alcoholism and cigarette smoking are indications for PPSV23 only.

Pneumococcal Vaccine (PCV15 or PCV20, PPSV23) for Persons 19-64 Years of Age with Underlying Conditions* Dose-0.5-mL, Route varies by product		
Age	Previous PCV or PPSV Vaccination History	Recommended Regimen/Route
19-64 years	PPSV23 only	1 dose of PCV20 or PCV15 IM
	PCV13 only	PPSV23 IM or SQ, if indicated
	PCV13 and PPSV23	No additional doses
	Unknown Vaccination History	1 dose of PCV20 IM; or PCV15 IM followed by PPSV23 IM or SQ

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*Alcoholism; chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy); cigarette smoking; diabetes mellitus; CSF leak; cochlear implant; sickle cell disease and other hemoglobinopathies; asplenia; HIV infection; chronic renal failure; nephrotic syndrome; immunodeficiency; diseases treated with immunosuppressive therapy or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; generalized malignancy; solid organ transplantation; or multiple myeloma

Routine Schedule* for PCV15 or PCV20, PPSV23 Dose and Route – 0.5-mL, Route varies by product			
Product/Route	Preferred Age	Preferred Spacing	Minimum Spacing
PCV20 or PCV15 IM	≥ 65		
PPSV23 [†] IM or SQ		≥ 1 year after PCV15	≥ 8 weeks after PCV15

*See recommendations for use for specific guidance.
[†]Indicated only for persons who received PCV15, and not for those who received PCV20. If PPSV23 is not available, one dose of PCV20 may be used.

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
Pneumococcal Conjugate Vaccines (PCV)				
Pevnar 20™ ¹	Sterile suspension of mixture of saccharides of the capsular antigens of <i>S. pneumoniae</i> , individually linked to non-toxic diphtheria CRM197 protein	0.5 mL prefilled syringes	≥ 18 years	None
VAXNEUVANCE™ ²		0.5 mL prefilled syringes	≥ 2 months	
Pevnar 13® ⁴		0.5 mL prefilled syringes	≥ 6 weeks	
Pneumococcal Polysaccharide Vaccine (PPSV23)				
Pneumovax 23® ³	Pneumococcal Vaccine Polyvalent is a sterile, liquid vaccine consisting of a mixture of purified capsular polysaccharides from <i>Streptococcus pneumoniae</i>	0.5 mL single dose vials	≥ 2 years	None
		0.5 mL prefilled syringes		

5. Recommendations for Use

A. Age 7-18 years:

- a. Chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma treated with high-dose, oral corticosteroids); diabetes mellitus:

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- i. Any incomplete series with PCV: no further PCV doses needed
 - ii. No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV doses)
 - b. Cerebrospinal fluid leak, cochlear implant:
 - i. No history of either PCV or PPSV23: 1 dose PCV, 1 dose PPSV23 at least 8 weeks later
 - ii. Any PCV but no PPSV23: 1 dose PPSV23 at least 8 weeks after the most recent dose of PCV
 - iii. PPSV23 but no PCV: 1 dose PCV at least 8 weeks after the most recent dose of PPSV23
 - c. Sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiency; HIV infection; chronic renal failure; nephrotic syndrome; malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and other diseases associated with treatment with immunosuppressive drugs or radiation therapy; solid organ transplantation; multiple myeloma:
 - i. No history of either PCV or PPSV23: 1 dose PCV, 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after PCV and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
 - ii. Any PCV but no PPSV23: 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after the most recent dose of PCV and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
 - iii. PPSV23 but no PCV: 1 dose PCV at least 8 weeks after the most recent PPSV23 dose and a dose 2 of PPSV23 administered 5 years after dose 1 of PPSV23 and at least 8 weeks after a dose of PCV
- B. Age 19–64 years:
 - a. Underlying medical conditions or other risk factors include alcoholism, chronic heart/liver/lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, CSF leak, diabetes mellitus, generalized malignancy, HIV, Hodgkin disease, immunodeficiency, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplants, or sickle cell disease, or other hemoglobinopathies
 - i. Not previously received a PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown: 1 dose PCV15 OR 1 dose PCV20. If PCV15 is used, this should be followed by a dose of PPSV23 given at least 1 year after the PCV15 dose.
 - 1. A minimum interval of 8 weeks between PCV15 and PPSV23 can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak
 - 2. Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid

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organ transplants, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies

- ii. Previously received only PCV7: follow the recommendation above
 - iii. Previously received only PCV13: 1 dose PCV20 at least 1 year after the PCV13 dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf
 - iv. Previously received only PPSV23: 1 dose PCV15 OR 1 dose PCV20 at least 1 year after the PPSV23 dose. If PCV15 is used, it need not be followed by another dose of PPSV23
 - v. Previously received both PCV13 and PPSV23 but have not completed the recommended series: 1 dose PCV20 at least 5 years after their last pneumococcal vaccine dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf
- C. Age 65 years or older:
- a. Not previously received a dose of PCV13, PCV15, or PCV20 or whose previous vaccination history is unknown: 1 dose PCV15 OR 1 dose PCV20. If PCV15 is used, this should be followed by a dose of PPSV23 given at least 1 year after the PCV15 dose
 - i. A minimum interval of 8 weeks between PCV15 and PPSV23 can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak to minimize the risk of invasive pneumococcal disease caused by serotypes unique to PPSV23 in these vulnerable groups.
 - ii. Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies.
 - b. Previously received only PCV7: follow the recommendation above.
 - c. Previously received only PCV13: 1 dose PCV20 at least 1 year after the PCV13 dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf
 - d. Previously received only PPSV23: 1 dose PCV15 OR 1 dose PCV20 at least 1 year after the PPSV23 dose. If PCV15 is used, it need not be followed by another dose of PPSV23.
 - e. Previously received both PCV13 and PPSV23 but NO PPSV23 was received at age 65 years or older: 1 dose PCV20 at least 5 years after their last pneumococcal vaccine dose OR complete the recommended PPSV23 series as described here: www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf
 - f. Previously received both PCV13 and PPSV23, AND PPSV23 was received at age 65 years or older: Adults aged 65 or older have the option to receive PCV20 if they previously completed the pneumococcal vaccine series with both PCV13 and PPSV23. This includes one dose of PCV13 at any age and all recommended doses of PPSV23, including one dose at or after age 65. PCV20 is not routinely recommended for these individuals as their risk of disease is lower due to prior vaccinations. Instead, ACIP recommends a

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PCV20 vaccination for persons aged 65 or older who have received both PCV13 and PPSV23 on the basis of shared clinical decision-making. Shared clinical decision-making refers to an individually based vaccine recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian. Pharmacists can engage in shared clinical decision making to discuss PCV20 vaccination with persons aged 65 or older who are most likely to benefit. Pharmacists are authorized to administer PCV20 vaccine if one of the following risk factors is present AND at least 5 years has elapsed since last pneumococcal vaccination:

- i. Persons living in nursing homes or other long-term care facilities
- ii. The presence of underlying medical conditions or other risk factors that increase the risk of developing severe disease (refer to Section 5.B.a. for list).

6. Contraindications

- A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.
- B. PCV20¹, PCV15², or PCV13⁴: Persons who experienced an anaphylactic reaction to a previous dose of any diphtheria toxoid-containing vaccine.
- C. PCV13⁴: Allergy to soy peptones.

7. Warnings and Precautions

- A. PPSV23: Care should be exercised when administering to patients with severely compromised cardiovascular or pulmonary function in whom a systemic reaction would pose a significant risk.³

8. Other Considerations

- A. Adults with previous PPSV23 only: Adults who have only received PPSV23 may receive a PCV (either PCV20 or PCV15) ≥ 1 year after their last PPSV23 dose. When PCV15 is used in those with history of PPSV23 receipt, it need not be followed by another dose of PPSV23.⁵
- B. Adults with previous PCV13: The incremental public health benefits of providing PCV15 or PCV20 to adults who have received PCV13 only or both PCV13 and PPSV23 have not been evaluated. These adults should complete the previously recommended PPSV23 series.⁵ One dose of PCV20 may replace the PPSV23 if PPSV23 is not available.
- C. Lactation: It is not known whether pneumococcal vaccines are excreted in human milk. Use with caution in people who are nursing.¹⁻⁴
- D. Pregnancy: Pneumococcal vaccine should be considered for persons at increased risk.¹⁰
- E. Simultaneous administration of PCV15 and PPSV23 is NOT recommended. See section 5, recommendations for use, for the necessary minimum interval between doses.^{5,7}
- F. Splenectomy, immunocompromising therapy, or cochlear implant: When elective splenectomy, immunocompromising therapy, or cochlear implant placement is being planned, age appropriate PCV vaccination should be completed at least 2 weeks before surgery or initiation of therapy. If vaccine is not administered before surgery, it should be administered ≥ 2 weeks after surgery. If the patient is unlikely to return, vaccine can be administered in the immediate postoperative period.⁹

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- G. Children who have experienced invasive pneumococcal disease should receive all recommended doses of a pneumococcal conjugate vaccine as appropriate for their age and underlying condition. The full series of scheduled doses should be completed even if the series is interrupted by an episode of invasive pneumococcal disease.⁹
- H. Individuals with diseases associated with immunosuppressive therapy or radiation therapy and solid organ transplantation may have a diminished response to the vaccine.¹⁻⁴
- I. Recipients of Hematopoietic Cell Transplants (HCT): ACIP recommends that patients be revaccinated with three sequential doses of age appropriate PCV vaccine beginning 3–6 months after HCT transplant. A dose of PPSV should be administered ≥8 weeks after the last dose of PCV.¹⁰

9. Side Effects and Adverse Reactions

PCV13⁴ Adverse Events	Frequency
Infants and children	
Irritability, soreness at the injection site	Up to 80%
Decreased appetite, decreased sleep, increased sleep	Up to 48%
Fever, erythema, induration at injection site	Up to 30%
Allergic reactions	Rare
PCV20¹, PCV15², PCV13⁴ Adverse Events	Frequency
Adults	
Soreness at the injection site, fatigue	Up to 76%
Headache, muscle pain, joint pain, decreased appetite, local swelling, decreased arm movement	Up to 30%
Vomiting, fever, chills, rash	Up to 30%
Allergic reactions	Rare
PPSV23³ Adverse Events	Frequency
Soreness, redness, swelling at the injection site	Up to 60%
Headache, muscle pain, fatigue	Up to 20%
Nausea, fever, chills	Rare, up to 2%
Allergic Reactions	Rare

10. Storage and Handling

- A. Store medications according to OAR 855-041-1036.
- B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
Prevnar 20™ ¹	Store at 2°– 8°C (36°- 46°F)	Store syringes horizontally to minimize re-suspension time; do not freeze	
VAXNEUVANCE™ ²		Do not freeze. Protect from light.	

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Prevnar® 13 ³	Vaccine is stable at temperatures up to 25 ° C for up to 4 days- not recommended for storage or shipping.
Pneumovax® 23 ⁴	None

11. References

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2. VAXNEUVANCE™ (PCV15), [Package insert]. July 2022. www.fda.gov/media/150819/download. Accessed 23 July 2023
3. Pneumovax®23 (PPSV23). [Package insert]. October 2021. <https://www.fda.gov/media/80547/download>. Accessed 23 July 2023.
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5. Kobayashi M, Farrar JL, Gierke R, et al. Use of 15-valent pneumococcal conjugate vaccine and 20-valent pneumococcal conjugate vaccine among U.S. adults: Updated recommendations of the Advisory Committee on Immunization Practices. MMWR 2022;71(4);109–17. Available at: <https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7137a3-H.pdf>. Accessed 23 July 2023.
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10. Kroger A, Bahta L, Long S, Sanchez P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). 20 June 2023. Available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf>. Accessed 23 July 2023.

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12. Appendix

- A. Centers for Disease Control and Prevention (CDC). Pneumococcal Vaccine Timing. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. <https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf>
- B. Centers for Disease Control and Prevention (CDC). Shared Clinical Decision-Making for Pneumococcal Conjugate Vaccine (PCV20) Vaccination in Adults Aged 19 Years or Older: Job Aid for Healthcare Professionals. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. <https://www.cdc.gov/vaccines/hcp/admin/downloads/job-aid-SCDM-PCV20-508.pdf>