Immunization Pharmacy Protocol

PNEUMOCOCCAL CONJUGATE VACCINE: PCV20 (Prevnar 20™), PCV15 (VAXNEUVANCE™), PCV13 (Prevnar 13®) AND PNEUMOCOCCAL POLYSACCHARIDE VACCINE: PPSV23 (Pneumovax®23)	
Last Reviewed	31 October 2022
Last Updated	31 October 2022
This order expires	31 October 2024

Table of contents

1. What's new 1
2. Oregon model immunization protocol 2
3. Vaccine schedule for pneumococcal vaccines 3
4. Licensed pneumococcal vaccines 3
5. Recommendations for use 3
6. Contraindications 5
7. Warnings and precautions 5
8. Other considerations 5
9. Side effects and adverse reactions 7
10. Storage and handling 7
11. Adverse events reporting 8
12. References 8

1. What's new

PCV15 has been approved by the FDA for use in children 7 years through 18 years of age. ACIP recommends that PCV15 and PCV13 may be used interchangeably in children.[5]

2. Oregon model immunization protocol

A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.

B. Screen clients for contraindications.

C. Provide a current Vaccine Information Statement (VIS), answering any questions.

D. Record all required data elements in the client's permanent health record.

E. Verify needle length for IM injection into the vastus lateralis or deltoid. PPSV23 may also be given by SQ injection into the fatty tissue over the triceps with a 5/8" needle.[3]

F. To avoid shoulder injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the deltoid muscle and use proper intramuscular administration technique.[12]

G. Pneumococcal vaccines:

   1) Give 0.5 mL PCV20 vaccine (Prevnar 20), PCV15 (VAXNEUVANCE), or PCV13 (Prevnar 13) intramuscularly (IM) to eligible clients. See Section 5. A–C; **OR**
   2) Give 0.5 mL PPSV23 vaccine (Pneumovax 23) IM, or subcutaneously (SC) to eligible clients. See Section 5. C-E.

H. Pneumococcal conjugate vaccines and PPSV23 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.[6]

I. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.[13]

I have read, understand, and agree to participate by the terms of this protocol.

Pharmacist Signature Date

3. Vaccine schedule for pneumococcal vaccines

Vaccine Schedule: Pneumococcal Conjugate Vaccine (PCV13 or PCV15)[6,10]			
Age Group	**Dose**	**No. of Doses**	**Route**
≥7 years	0.5 mL	Varies by age	Intramuscular
Vaccine Schedule: Pneumococcal Conjugate Vaccine (PCV20)[6]			
Age Group	**Dose**	**No. of Doses**	**Route**
≥19 years	0.5 mL	1	Intramuscular
Vaccine Schedule: Pneumococcal Polysaccharide Vaccine (PPSV23)[7]			
Age Group	**Dose**	**No. of Doses**	**Route**
≥7 years	0.5 mL	Varies by age	Intramuscular or Subcutaneous

4. Licensed pneumococcal vaccines

Pneumococcal Conjugate Vaccines		
Trade Name	**Presentation**	**Acceptable Age Range**
Prevnar 20™[1]	0.5-mL prefilled syringes	≥19 years
VAXNEUVANCE™[2]	0.5-mL prefilled syringes	≥7 years
Prevnar 13®[4]	0.5-mL prefilled syringes	≥7 years
Pneumococcal Polysaccharide Vaccine (PPSV23)		
Trade Name	**Presentation**	**Acceptable Age Range**
Pneumovax 23®[3]	0.5-mL single-dose vials 0.5-mL prefilled syringes	≥7 years

5. Recommendations for use

A. Persons with Special Indications[9]

Pneumococcal Vaccine (PCV13 or PCV15 and PPSV) for Persons 7–18 Years of Age with Underlying Conditions				
Age	**Previous PCV13 Vaccination History**	**Previous PPSV Vaccination History**	**Due Now#** (≥8 weeks since last pneumo)	**Due Next**

7–18 years of age with high-risk* conditions	Unvaccinated	Unvaccinated	PCV13 or PCV15	PPSV in ≥8 weeks. Revaccinate with PPSV in 5 years
		1 dose	PCV13 or PCV15	Revaccinate with PPSV in 5 years
	≥1 dose of PCV13	Unvaccinated	PPSV	Revaccinate with PPSV 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.

B. Routine Schedule for PCV20 or PCV15

All persons ≥65 years of age should receive a single dose of PCV20 or doses of PCV15 and PPSV in series.[6,7]

Routine Pneumococcal Vaccine			
Dose	**Preferred Age**	**Preferred Spacing**	**Minimum Spacing**
PCV20 or PCV15	≥65 years		
PPSV*		≥1 year after PCV15	≥8 weeks after PCV15

*Indicated only for persons who received PCV15, and not for those who received PCV20. If PPSV is not available, one dose of PCV20 may be used.

C. Persons with Special Indications for PCV20 or PCV15[6]

Pneumococcal Conjugate Vaccine (PCV20 or PCV15) for Persons 19–64 Years of Age with Underlying Conditions*		
Age	**Previous PCV or PPSV Vaccination History**	**Recommended Regimen**
19–64 years	PPSV only	1 dose of PCV20 or PCV15
	PCV13 only	PPSV, if indicated
	PCV13 and PPSV	No additional doses
	Unknown Vaccination History	1 dose of PCV20; or PCV15 followed by PPSV

*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.

6. Contraindications

PCV20[1], PCV15[2], or PCV13[4]

Persons who experienced an anaphylactic reaction to a previous dose of any pneumococcal conjugate vaccine, any vaccine component, or any diphtheria toxoid-containing vaccine.

PCV13[4]

Allergy to soy peptones.

PPSV23[3]

Persons who experienced an anaphylactic reaction to a previous dose of pneumococcal vaccine or a vaccine component.

7. Warnings and precautions

Persons with acute, moderate, or severe illness with or without fever may choose to delay immunization until symptoms have improved.[13]

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.[6]

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.[6] One dose of PCV20 may replace the PPSV if PPSV is not available.

C. **Adverse Events**: Epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.[13]

D. **Lactation**: It is not known whether pneumococcal vaccines are excreted in human milk. Use with caution in people who are nursing.[1-4]

E. **Pregnancy**: Pneumococcal vaccine should be considered for persons at increased risk.[13]

F. Simultaneous administration of PCV15 and PPSV23 is NOT recommended. See sections 5, recommendations for use, for the necessary minimum interval between doses.[6,8]

G. May give influenza and zoster vaccines at same visit as PPSV23.[7]

H. **Splenectomy, immunocompromising therapy, or cochlear implant:**

For children ≤18 years of age: When elective splenectomy, immunocompromising therapy, or cochlear implant placement is being planned, p vaccination should be completed at least 2 weeks before surgery or initiation of therapy. If pneumococcal 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 post-operative period.[10]

For adults ≥19 years of age: When elective splenectomy, immunocompromising therapy, or cochlear implant placement is being planned, pneumococcal vaccination should be completed at least 2 weeks before surgery or initiation of therapy. If PCV 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 post-operative period.[10]

I. Immunization should precede the initiation of immunocompromising therapy by at least two weeks.[10]

J. 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.[10]

K. Individuals with diseases associated with immunosuppressive therapy or radiation therapy and solid organ transplantation may have a diminished response to the vaccine.[1-4]

L. Recipients of Hematopoietic Cell Transplants (HCT):

For children ≤18 years of age: ACIP recommends that patients be revaccinated with three sequential doses of PCV13 (or PCV15) vaccine beginning 3–6 months after HCT transplant. A dose of PPSV should be administered ≥8 weeks after the last dose of PCV.[13]

For adults ≥19 years of age: ACIP recommends that patients be revaccinated with three, sequential doses of PCV vaccine beginning 3–6 months after HCT transplant. A dose of PPSV should be administered ≥8 weeks after the last dose of PCV.[13]

9. Side effects and adverse reactions

PCV13[4]	
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
PCV20[1], PCV15[2], PCV13[4]	
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 5%
Allergic reactions	Rare
PPSV23[3]	
Soreness, redness, swelling at the injection site	Common, up to 60%
Headache, muscle pain, fatigue	Uncommon, up to 20%
Nausea, fever, chills	Rare, up to 2%
Allergic reactions	Rare

10. Storage and handling

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 (4832).

Vaccine	Discard	Latex	Temp	Storage Issues
Prevnar 20[1]	N/A	No	2°– 8°C	Store syringes horizontally to minimize resuspension time. Do not freeze.
VAXNEUVANCE[2]				Do not freeze. Protect from light.
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]	Use opened multi-dose vials through the expiration date			None

11. Adverse events reporting

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html.

VAERS Reporting Table: https://vaers.hhs.gov/resources/infoproviders.html

Event and interval from vaccination
A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval—not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval—see package insert).

12. References

1. Pfizer. Prevnar 20™ (PCV20) 2022 package insert. Available at: www.fda.gov/media/149987/download. Accessed 24 Oct 2022.
2. Merck and Co. VAXNEUVANCE™ (PCV15) 2022 package insert. Available at: www.fda.gov/media/150819/download. Accessed 24 Oct 2022.
3. Merck and Co. Pneumovax®23 (PPSV23) 2019 package insert. Available at: www.merck.com/product/usa/pi_circulars/p/pneumovax_23/pneumovax_pi.pdf. Accessed 24 Oct 2022.
4. Wyeth Pharmaceuticals, Inc. Prevnar®13 (PCV13) 2019 package insert. Available

at: http://labeling.pfizer.com/showlabeling.aspx?id=501. Accessed 24 Oct 2022.

5. Kobayashi M, Farrar JL, Gierke R, et al. Use of 15-valent pneumococcal conjugate vaccine among U.S. children: Updated recommendations of the Advisory Committee on Immunization Practices. MMWR 2022;71(37);1174–1181. Accessed 24 Oct 2022.
6. 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. Accessed 24 Oct 2022.
7. Matanock A, Lee G, Gierke R, et al. Use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine among adults aged ≥65 years: updated recommendations of the Advisory Committee on Immunization Practices. MMWR 2019;68(46);1069–75. Accessed 24 Oct 2022.
8. Kobayashi M, Bennett NM, Gierke R, et al. Intervals between PCV13 and PPSV23 vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2015;64(34):944–7. Accessed 24 Oct 2022.
9. 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). MMWR 2013;62(25):521–4. Accessed 24 Oct 2022.
10. Nuorti JP, Whitney CG. Prevention of pneumococcal disease among infants and children — use of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2010;59(RR11);1–18. Accessed 24 Oct 2022.
11. CDC. 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). MMWR 2012;61(40):816–9. Accessed 24 Oct 2022.
12. MacNeil JR, Rubin L, McNamara L, Briere EC, Clark TA, Cohn AC. Use of MenACWY-CRM vaccine in children aged 2 through 23 months at increased risk for meningococcal disease: recommendations of the Advisory Committee on Immunization Practices, 2013. MMWR 2014; 63(24):527–30. Accessed 24 Oct 2022.
13. Ezeanolue E, Harriman K, Hunter P, Kroger A. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP). Accessed 24 Oct 2022.