

# **Model Immunization Protocol**

PNEUMOCOCCAL CONJUGATE VACCINE: PCV20 (Prevnar 20™),
PCV15 (VAXNEUVANCE™), PCV13 (Prevnar 13®)
AND PNEUMOCOCCAL POLYSACCHARIDE VACCINE: PPSV23
(Pneumovax®23)

Last Reviewed

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This order expires

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## 1. What's new

PCV20 has been recommended by the ACIP for routine use in children <5 years of age and in children ≤18 years of age who have a high-risk condition. PCV20 and PCV15 are interchangeable.

Added shared clinical decision-making for adults 65 years of age or older who previously received both PCV13 and PPSV23.

## 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.<sup>3</sup>
- 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.<sup>12</sup>
- 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.<sup>6</sup>
- I. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.<sup>13</sup>

Health Officer Signature	Date
Health Officer Signature	Date

# 3. Vaccine schedule for pneumococcal vaccines

Vaccine Schedule: Pneumococcal Conjugate Vaccine (PCV13, PCV15, or PCV20) <sup>6,10</sup>						
Age Group	Dose	No. of Doses	Route			
≥6 weeks	0.5 mL	Varies by age	Intramuscular			
Vaccine Sch	Vaccine Schedule: Pneumococcal Conjugate Vaccine (PCV20) <sup>6</sup>					
Age Group	Dose	No. of Doses	Route			
≥19 years 0.5 mL 1		Intramuscular				
Vaccine Schedule: Pneumococcal Polysaccharide Vaccine (PPSV23) <sup>7</sup>						
Age Group	Dose	No. of Doses	Route			
≥2 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				
VAXNEUVANCE™2	0.5-mL prefilled syringes	≥6 weeks			
Prevnar 13®4	0.5-mL prefilled syringes				
Pneumo	Pneumococcal Polysaccharide Vaccine (PPSV23)				
Trade Name	Presentation	Acceptable Age Range			
Pneumovax 23®3	0.5-mL single-dose vials	>2 years			
Fileuillovax 20°°	0.5-mL prefilled syringes	≥2 years			

# 5. Recommendations for use

A. Routine Schedule for PCV vaccines

All infants aged ≥2 months without contraindications. First dose may be given as early as 6 weeks of age.

Routine Pneumococcal Conjugate Vaccine <sup>10</sup> (PCV13, PCV15 or PCV20)				
Dose	Preferred age	Minimum acceptable	Minimum acceptable	
		age	spacing	

1	2 months	6 weeks	
2	4 months	10 weeks	4 weeks after dose 1
3	6 months	14 weeks	4 weeks after dose 2
4	12-15 months	12 months	8 weeks after dose 3

# B. Catch-Up Schedule for PCV vaccines

	Catch-up Pneumococcal Conjugate Vaccine (PCV13, PCV15 or PCV20)					
Age Doses received previously		Recommended PCV regimen	Total doses in series			
	0 doses	3 doses, 4 weeks apart; 4 <sup>th</sup> dose at 12-15 months	4			
4-6 months	1 dose	2 doses, 4 weeks apart; 4 <sup>th</sup> dose at age 12-15 months	4			
	2 doses	1 dose, 4 weeks after most recent dose; 4th dose at 12-15 months	4			
7-11	0 doses	2 doses, 4 weeks apart; 3 <sup>rd</sup> dose at 12-15 months	3			
months	1 or 2 doses before 7 months of age	1 dose at 7–11 months, with a 2nd dose at 12–15 months ≥8 weeks afterwards	3 or 4			
	0 doses	2 doses ≥8 weeks apart	2			
12-23	1 dose <12 months of age	2 doses ≥8 weeks apart	3			
months	1 dose ≥12 months of age	1 dose ≥8 weeks after the most recent dose	2			
	2 or 3 doses at <12 months of age	1 dose ≥8 weeks after the most recent dose	3 or 4			
	0 doses	1 dose	1			
	1 dose	1 dose	2			
24 50	2 doses <24 months of age	1 dose	3			
24-59 months	2 doses, at least 1 dose at ≥12 months of age	Series complete	2			
	3 doses, <12 months of age	1 dose	4			

3 doses, at least 1	Series complete	3
dose at ≥12		
months of age		

## C. Persons with Special Indications<sup>9</sup>

# Pneumococcal Vaccine (PCV15 or PCV20 and PPSV) for Persons 2–18 Years of Age with Underlying Conditions\*

2–18 Years of Age with Underlying Conditions*					
Age	Previous PCV Vaccination History	Previous PPSV Vaccination History	Due Now (≥8 weeks since last pneumo)	Due Next	
	Unvaccinated or incomplete series of ≤2	Unvaccinated	PCV15 or PCV20	PCV15 or PCV20 in ≥8 weeks	
2-5 years	doses	1 dose		WCCKS	
of age with chronic	Incomplete series of 3	Unvaccinated	PCV15 or PCV20		
conditions	doses	1 dose			
	4 doses before	Unvaccinated			
	age 24 months	1 dose			
	Unvaccinated	Unvaccinated	PCV15 or PCV20	If PCV15, administer PPSV in ≥8 weeks.	
		1 dose	PCV15 or PCV20	If PCV15, administer PPSV in ≥8 weeks.	
6–18 years of	Completed childhood	Unvaccinated	PCV20 or PPSV	If PPSV, revaccinate with PCV20 or PPSV in 5 years	
age with high-risk* conditions	series with PCV13 or PCV15	1 dose	Dose due 5 years after last dose	Revaccinate with PCV20 or PPSV in 5 years	
	Completed childhood series which included ≥1 dose of PCV20	None	Complete	No additional doses indicated	

<sup>\*</sup>Chronic heart, kidney or liver disease, chronic lung disease (including moderate or severe persistent asthma), CSF leak, cochlear implant, sickle cell disease and other hemoglobinopathies, asplenia, HIV infection, 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.

#### D. 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.<sup>6,7</sup>

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

<sup>\*</sup>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.

#### E. Persons with Special Indications for PCV20 or PCV156

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	

<sup>\*</sup>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.

## F. Shared clinical decision-making for patients 65 years of age or older:

Patients who have previously received both PCV13 and PPSV23 may also receive PCV20 ≥5 years or more since the last dose of pneumococcal vaccine based on shared clinical decision-making.

PCV20 is not routinely recommended, however certain patients are at increased risk of exposure or increased risk of serious disease, including:

- Seniors living in nursing homes or other long-term care facilities;
- Seniors living in areas with low pediatric pneumococcal conjugate vaccine uptake;
- Seniors with immunocompromising conditions;
- Seniors with cochlear implants;
- Seniors with cerebrospinal fluid leak;
- More than one of these chronic medical conditions: alcoholism; chronic heart, liver, or lung disease; cigarette smoking; or diabetes.

#### 6. Contraindications

## PCV20<sup>1</sup>, PCV15<sup>2</sup>, or PCV13<sup>4</sup>

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<sup>4</sup>

Allergy to soy peptones.

## PPSV23<sup>3</sup>

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.<sup>13</sup>

#### 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.<sup>3</sup>

#### 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.<sup>6</sup>

- 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.<sup>6</sup> 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.<sup>13</sup>
- D. **Lactation**: It is not known whether pneumococcal vaccines are excreted in human milk. Use with caution in people who are nursing.<sup>1-4</sup>
- E. **Pregnancy**: Pneumococcal vaccine should be considered for persons at increased risk.<sup>13</sup>
- F. Simultaneous administration of PCV15 and PPSV23 is NOT recommended. See sections 5, recommendations for use, for the necessary minimum interval between doses.<sup>6,8</sup>
- 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, 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.<sup>10</sup>

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.<sup>10</sup>

- I. Immunization should precede the initiation of immunocompromising therapy by at least two weeks.<sup>10</sup>
- 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.<sup>10</sup>

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

## L. Recipients of Hematopoietic Cell Transplants (HCT):

For children ≤18 years of age: ACIP recommends that patients be revaccinated with three sequential doses of PCV20 vaccine beginning 3–6 months after HCT transplant. A fourth dose of PCV20 is recommended at least 6 months after the third PCV20 dose, or at least 12 months after HSCT, whichever is later.<sup>13</sup>

**If PCV20** is not available, three doses of PCV15, followed by a dose of PPSV23 at least 12 months after HSCT may be given. For patients with chronic graft-versus-host disease who are receiving PCV15, a fourth dose PCV15 dose can be given in place of PPSV23.<sup>13</sup>

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.<sup>13</sup>

#### 9. Side effects and adverse reactions

PCV13 <sup>4</sup> , PCV15 <sup>2</sup> , PCV20 <sup>1</sup>				
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 <sup>1</sup> , PCV15 <sup>2</sup> , PCV13 <sup>4</sup>				
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 <sup>3</sup>				

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 <u>immediately</u> report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4832).

Vaccine	Discard	Latex	Temp	Storage Issues
Prevnar 20 <sup>1</sup>	- N/A	No	2°-8°C	Store syringes horizontally to minimize resuspension time. Do not freeze.
VAXNEUVANCE <sup>2</sup>				Do not freeze. Protect from light.
Prevnar 13 <sup>3</sup>				Vaccine is stable at temperatures up to 25°C for up to 4 days—not recommended for storage or shipping
Pneumovax 23 <sup>4</sup>	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 <a href="https://vaers.hhs.gov/reportevent.html">https://vaers.hhs.gov/reportevent.html</a>.

VAERS Reporting Table: <a href="https://vaers.hhs.gov/resources/infoproviders.html">https://vaers.hhs.gov/resources/infoproviders.html</a>

#### **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).

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