Immunizing Pharmacist Protocol

PNEUMOCOCCAL CONJUGATE VACCINE: PCV13 (Prevnar®13) AND PNEUMOCOCCAL POLYSACCHARIDE VACCINE: PPSV23 (Pneumovax®23)	
Last Reviewed	21 August 2020
Last Updated	4 June 2020
This order expires	30 June 2022

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What's new[3]

PCV13 is no longer routinely recommended for all healthy adults ≥65 years due to sharp declines in pneumococcal disease among adults and children. Immunizing pharmacists MUST have a prescription in order to vaccinate this population

Adults with certain immunocompromising conditions should still receive a dose of PCV13 at age 65 years.

The decision of whether to vaccinate an adult ≥65 years of age who does not have an immunocompromising condition and who has not previously received PCV13 should be a shared clinical decision between the patient and their medical provider.

1. Oregon immunization pharmacy 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.

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.[9] See appendices for additional information.

G. Pneumococcal vaccines:

1) Give 0.5mL PCV13 vaccine (Prevnar®13)[2] intramuscularly (**IM**) to eligible clients. See Section 5. A–C; **OR**
2) Give 0.5 mL PPSV23 vaccine (Pneumovax ®23)[1] **IM**, or subcutaneously (**SC**) to eligible clients. See Section 6. I.

H. PCV13 and PPSV23 should **not** be given at the same time.[4] Either vaccine may be given simultaneously with influenza and most ACIP-recommended child and adult vaccinations.

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

J. This order does **not** cover Advisory Committee on Immunization Practices (ACIP) recommendations that involve shared clinical decision making. Shared clinical decision making means the decision to vaccinate should be based on a discussion of benefits and risks between the patient and the clinician, and the clinician would then prescribe the vaccine.

Pharmacist Signature Date

2. Vaccine schedule for pneumococcal vaccines

Vaccine Schedule: Pneumococcal Conjugate Vaccine (PCV13)[2]			
Age Group	Dose	No. of Doses	Route
≥ 7 years	0.5 mL	1	Intramuscular
Vaccine Schedule: Pneumococcal Polysaccharide Vaccine (PPSV23)[1]			
Age Group	Dose	No. of Doses	Route
≥ 7 years	0.5 mL	Varies by age	Intramuscular or Subcutaneous

3. Licensed pneumococcal vaccines

Pneumococcal Conjugate Vaccine (PCV13)		
Trade Name	Presentation	Acceptable Age Range
Prevnar 13®[2]	0.5 mL prefilled syringes	≥ 7 years
Pneumococcal Polysaccharide Vaccine (PPSV23)		
Trade Name	Presentation	Acceptable Age Range
Pneumovax 23®[1]	0.5 mL single dose vials	≥ 7 years
	0.5 prefilled syringes	
	2.5 mL five-dose vial	

5. Recommendations for use of PCV13

Persons with Special Indications for PCV13

Pneumococcal Conjugate Vaccine (PCV13) for Persons Aged ≥7 Years of Age with Underlying Conditions		
Age	Previous PCV Vaccination History	Recommended PCV13 Regimen
7–18 years of age with high-risk* conditions[5]	Unvaccinated with PCV13	1 dose ≥ 8 weeks after PPV23
	≥1 dose of PCV13	Complete
≥19 years of age with high-risk* conditions [1]	Unvaccinated with PCV13 or PPSV23	1 dose
	≥1 dose of PCV13	Complete
	Previous vaccination with PPSV23	1 dose ≥1 year after the last PPSV23 dose

*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. Recommendations for use of PPSV23

A. Routine Schedule for PPSV23

Routine Pneumococcal Polysaccharide Vaccine (PPSV23)		
Age	Previous PPSV23 Vaccination History	Recommended PPSV23 Regimen
≥65 years[1,3]	Unvaccinated	1 dose
	≥ 1 previous dose ≤ 65 years	1 dose ≥ 5 years after previous dose
	≥ 1 previous dose ≥ 65 years	Complete

B. Persons with Special Indications for PPSV23

Pneumococcal Polysaccharide Vaccine (PPSV23) for Children Aged ≥7 Years of Age and Adults with Underlying Conditions[7]			
Age	Previous PPSV23 Vaccination History	Recommended PPSV23 Regimen	Revaccinate after 5 years?
≥7 years - **immunocompetent** with chronic conditions•[6]	Unvaccinated	1 dose ≥8 weeks after any PCV doses	No
	1 dose	Complete	No
≥7 years - **immunocompromised** with high-risk conditions*[6,7]	Unvaccinated	1 dose ≥8 weeks after any PCV doses	Yes, then final dose at age 65 years
	1 dose	1 dose ≥ 5 years after last dose and ≥8 weeks after any PCV doses.	No, final dose at age 65 years
• Chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure), chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy), chronic liver disease, diabetes mellitus, alcoholism, cigarette smoking.			
*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

PCV13[2]

A. Persons who experienced an anaphylactic reaction to a previous dose of PCV7, PCV13 or any diphtheria toxoid-containing vaccine.

B. Allergy to soy peptones.

PPSV23[1]

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

7. Warnings and precautions

PCV13 and PPSV23[1, 2]

A. Women who are at high risk of pneumococcal disease and who are candidates for either PCV13 or PPSV23 should be vaccinated before pregnancy, if possible.

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

PPSV23[1]

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

8. Other considerations

A. **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.[9]

B. **Lactation**: It is not known whether pneumococcal vaccines are excreted in human milk. Use with caution in nursing mothers.[1, 2]

C. Simultaneous administration of PCV13 and PPSV23 is NOT recommended. See section 5 and 6, recommendations for use, for the necessary minimum interval between doses.[4]

D. May give influenza and/or zoster vaccines at same visit as PPSV23.[1]

E. When an elective splenectomy is performed for any reason, administer PPSV23 at least 8 weeks after the last dose of PCV13 and at least 2 weeks prior to splenectomy. 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.[6]

F. Immunization should precede the initiation of immunocompromising therapy by at least two weeks.[6]

G. Individuals with diseases associated with immunosuppressive therapy or radiation therapy and solid organ transplantation may have a diminished response to the vaccine.[1, 2]

H. ACIP recommends that one dose of PPSV23 be given to a hematopoietic stem cell transplant (HSCT) recipient ≥8 weeks the last dose of PCV13.[8]

9. Side effects and adverse reactions

PCV13[2]	
Children	
Irritability, soreness at the injection site	Very common, up to 80%
Decreased appetite, decreased sleep, increased sleep	Common, up to 50%
Fever, erythema, induration at injection site	Common, up to 30%
Allergic reactions	Rare
Adults	
Soreness at the injection site, fatigue	Common, up to 50%
Headache, muscle pain, joint pain, decreased appetite, local swelling, decreased arm movement	Uncommon, up to 20%
Vomiting, fever, chills, rash	Rare, up to 5%
Allergic reactions	Rare
PPSV23[1]	
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 (4823).

Vaccine	Discard	Latex	Temp	Storage Issues
Prevnar 13[2]	N/A	No	2◦ – 8◦C	Vaccine is stable at temperatures up to 25◦C for up to 4 days – not recommended for storage or shipping
Pneumovax 23[1]	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. Merck and Co. PPV23 (Pneumovax®23) 2019 package insert. Available at: https://www.merck.com/product/usa/pi_circulars/p/pneumovax_23/pneumovax_pi.pdf
2. Wyeth Pharmaceuticals, Inc. PCV13 (Prevnar®13) 2019 package insert. Available at: http://labeling.pfizer.com/showlabeling.aspx?id=501
3. Almea Matanock, MD; Grace Lee, MD; Ryan Gierke, MPH; Miwako Kobayashi, MD; Andrew Leidner, PhD; Tamara Pilishvili, PhD. 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);1069–1075. Accessed 11 December 2019
4. Kobayashi M, Bennett NM, Gierke R, Almendares O, Moore MR, Whitney CG, et al. Intervals between PCV13 and PPSV23 vaccines: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2015;64(34):944-947 Accessed 11 December 2019
5. 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):521-524 Accessed 11 December 2019
6. 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

7. Use pf 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):816-819 Accessed 27 January 2020
8. 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 on 19 December 2019.

13. Appendices

Table 1

ACIP RECOMMENDATIONS FOR SEQUENTIAL ADMINISTRATION AND RECOMMENDED INTERVALS FOR PNEUMOCOCCAL VACCINE-NAÏVE HIGH-RISK PERSONS 19–64 YEARS OF AGE: [4]

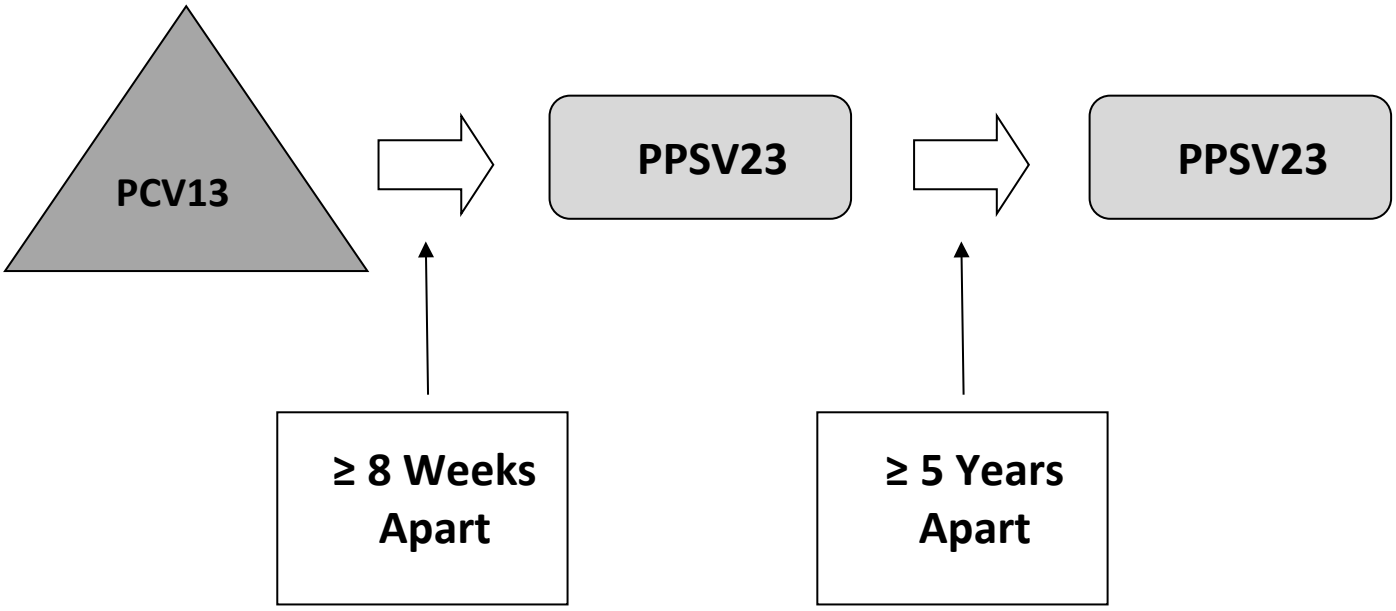
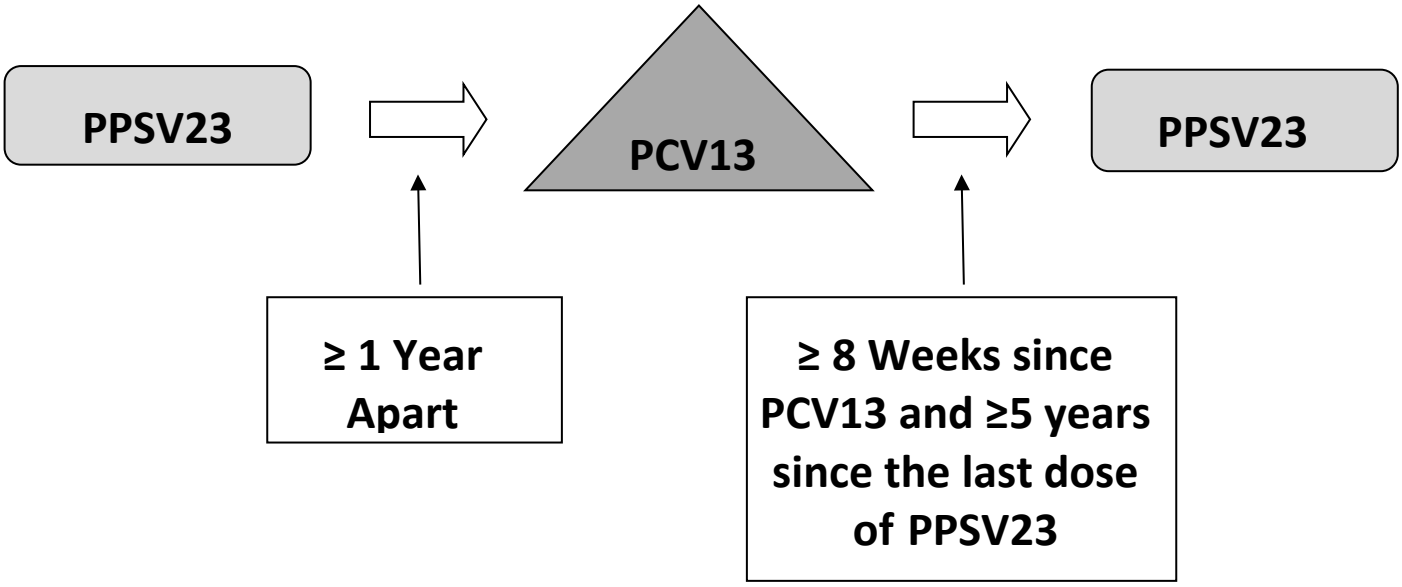


Table 2

ACIP RECOMMENDATIONS FOR SEQUENTIAL ADMINISTRATION AND RECOMMENDED INTERVALS FOR HIGH-RISK PERSONS 19–64 YEARS OF AGE WITH PRIMARY PPSV23 IMMUNIZATION: [3]



YOU CALL THE SHOTS

Shoulder injuries related to vaccine administration
Improper vaccine administration could result in shoulder injuries such as shoulder bursitis and tendinitis.

Make sure vaccination is safe.

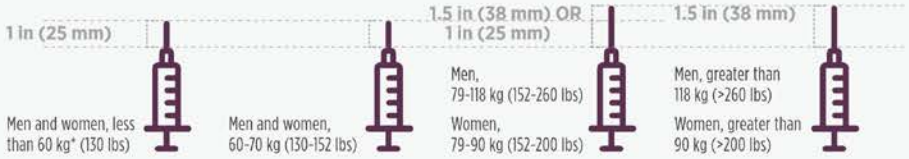
KNOW THE SITE. GET IT RIGHT!

When administering vaccine by an intramuscular (IM) injection to an adult:

Use the correct syringe and needle

- Vaccine may be administered using either a 1-mL or 3-mL syringe
- Use a 22 to 25 gauge needle
- Use the correct needle size based on your patient's size

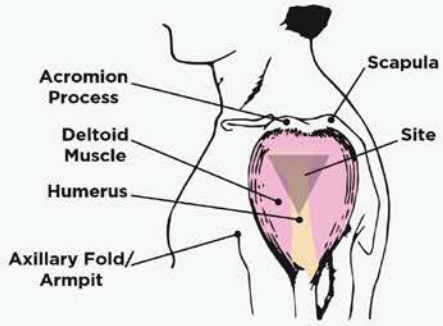
Injection site: Deltoid muscle of upper arm



*Some experts recommend a 5/8-inch needle for men and women who weigh less than 60 kg (130 lbs).

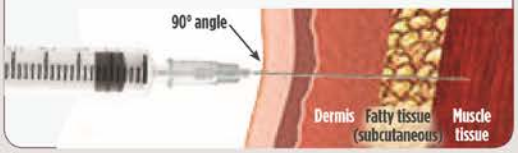
Identify the injection site

- Locate the deltoid muscle of the upper arm
- Use anatomical landmarks to determine the injection site
- In adults, the midpoint of the deltoid is about 2 inches (or 2 to 3 fingers' breadth) below the acromion process (bony prominence) and above the armpit in the middle of the upper arm



Administer the vaccine correctly

- Inject the vaccine into the middle and thickest part of the deltoid muscle
- Insert the needle at a 90° angle and inject all of the vaccine into the muscle tissue



Always follow safe injection practices

- Maintain aseptic technique
- Perform hand hygiene before preparing and administering vaccines
- Use a new needle and new syringe for each injection
- If using a single-dose vial (SDV) discard after use

A SDV should be used for one patient only!

IM injection best practices

- Administering the injection too high on the upper arm may cause shoulder injury
- If administering additional vaccines into the same arm, separate the injection sites by 1 inch if possible

Report any clinically significant adverse event after vaccination to the Vaccine Adverse Event Reporting System (VAERS) at vaers.hhs.gov/

For additional information on proper vaccine administration, visit the CDC vaccine administration web page at www.cdc.gov/vaccines/hcp/admin/admin-protocols.html

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U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Remember—you call the shots when it comes to proper flu vaccine administration!