

**OREGON HEALTH AUTHORITY  
IMMUNIZATION PROGRAM  
PNEUMOCOCCAL CONJUGATE VACCINE (PCV13)**

- Date Formatting and Adverse Events Reporting link change.
- PCV13 is routinely recommended for children 6–18 years of age who have immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants who have not previously received PCV13 regardless of whether they received PCV7 or PPV23: this recommendation has gone from an off-label recommendation to a category A recommendation in the pediatric immunocompromised population.

**I. ORDER:**

1. Check the ALERT Immunization Information System to determine whether the patient needs this vaccine and any other vaccines.
2. Screen for contraindications.
3. Provide a current Vaccine Information Statement (VIS), answering any questions.
4. Obtain a signed Vaccine Administration Record (VAR).
5. Give 0.5 ml PCV13 vaccine intramuscularly (IM).
6. May be given simultaneously with most other routine childhood immunizations; Note febrile seizure precaution (p 9) for children <5 years of age receiving PCV13 and TIV concomitantly.
7. Concurrent administration of pneumococcal conjugate and pneumococcal polysaccharide (PPV23) vaccines is not recommended. The safety and efficacy of concurrent vaccination has not been studied.

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Signature

Health Officer or Medical Provider

Date

## II. U.S. LICENSED PNEUMOCOCCAL CONJUGATE VACCINE

Product Name	Vaccine component(s)	Age Range	FDA Approved?
Pevnar 13® (Wyeth/Pfizer)	Polysaccharide conjugate of 13 serotypes of <i>Streptococcus pneumoniae</i>	6 weeks – 5 years	Yes
		6–18 years with selected high-risk conditions	Yes
		19–49 years with selected high-risk conditions <sup>1</sup>	No <sup>1</sup>
		≥50 years of age	Yes

<sup>1</sup>ACIP's off-label provisional recommendations advise that children and adults with selected high-risk conditions should receive this vaccine (See Section IV, Table 3, p 6 and Section VII. p 8).

### III. RECOMMENDATIONS FOR USE

#### Persons for whom PCV13 is recommended

1. All children 2–59 months of age who are unvaccinated or incompletely vaccinated with pneumococcal conjugate vaccine.<sup>1</sup>
2. All children 14–59 months of age who have completed the PCV7 series.
3. Children 60–71 months of age with any of these underlying medical conditions:
  - Sickle cell disease and other sickle cell hemoglobinopathies, congenital or acquired asplenia<sup>1</sup>, or splenic dysfunction;
  - Infection with HIV;
  - Immunocompromising conditions, including
    - ◆ Congenital immunodeficiencies: B- (humoral) or T-lymphocyte deficiency; complement deficiencies, particularly c1, c2, c3, or c4 deficiency; and phagocytic disorders, excluding chronic granulomatous disease;
    - ◆ Renal failure or nephrotic syndrome; and
    - ◆ Diseases associated with immunosuppressive therapy or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin's disease; or solid organ transplantation;
  - Chronic illness, including
    - ◆ Chronic cardiac disease, particularly cyanotic congenital heart disease and cardiac failure;
    - ◆ Chronic pulmonary disease, excluding asthma unless on high dose corticosteroid therapy;
    - ◆ Cerebrospinal fluid leaks;
    - ◆ Diabetes mellitus; and
    - ◆ Cochlear implants
4. Persons ≥6 years of age with immunocompromising conditions (i.e. HIV & sickle cell disease), functional or anatomic asplenia, CSF leaks or cochlear implants, regardless of whether they have previously received PCV7 or PPV23. See Section 7 on page 8.
5. Adults ≥19 years of age with high-risk conditions noted in section VII on page 8.

<sup>1</sup> ACIP recommends that PCV13 and MCV4 (Menactra) be administered ≥30 days apart for children in this age group with asplenia to avoid co-administration interference.

#### IV. VACCINE SCHEDULES

**Table 1. Primary PCV13 Series and booster for infants 6–15 months of age**

<b>DOSE</b>	<b>MINIMUM AGE<sup>1</sup></b>	<b>MINIMUM SPACING<sup>1,2</sup></b>	<b>RECOMMENDED AGE</b>
1	6 weeks		2 months
2	10 weeks	4 weeks after dose #1	4 months
3	14 weeks	4 weeks after dose #2	6 months
4 (booster)	12 months	8 weeks after dose #3	12–15 months

<sup>1</sup> For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not need to be repeated. Doses administered 5 days or earlier than the minimum interval or age should be repeated as appropriate for age.

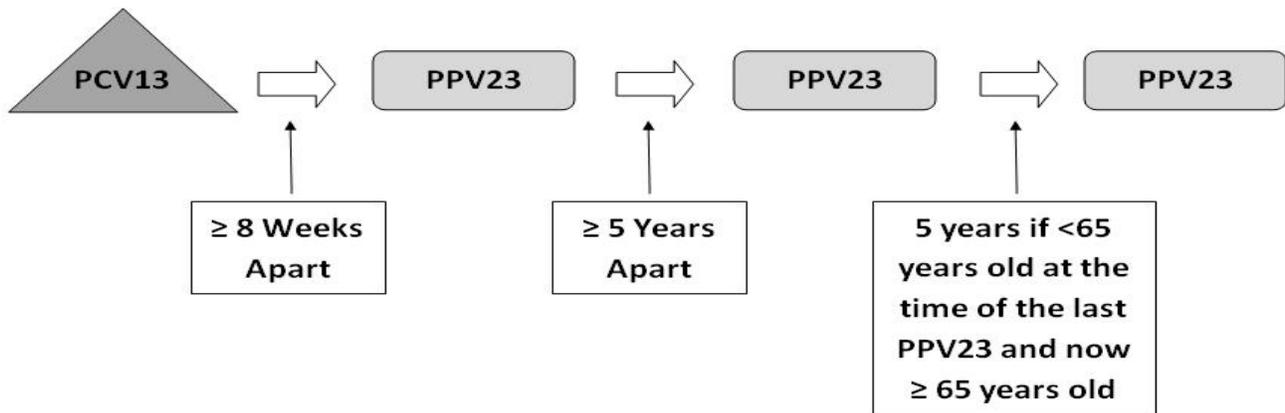
<sup>2</sup> When an invalid dose occurs due to dose spacing it will need to be repeated. The repeat dose should be spaced after the invalid dose by a time equal to or greater than the minimum interval between doses.

<b>Table 2. Doses of PCV13 to children &lt;24 months of age</b>		
<b>Age</b>	<b>Vaccination history: # of PCV7 and PCV13 doses received previously</b>	<b>RECOMMENDED PCV13 regimen<sup>1</sup></b>
2–6 months	0 doses	3 doses, 8 weeks apart; 4 <sup>th</sup> dose at age 12–15 mos
	1 dose	2 doses, 8 weeks apart; 4 <sup>th</sup> dose at age 12–15 mos
	2 doses	1 dose, 8 weeks after most recent dose; 4 <sup>th</sup> dose at 12–15 mos
7–11 months	0 doses	2 doses, 8 weeks apart; 3 <sup>rd</sup> dose at 12–15 mos
	1 or 2 doses before age 7 mos	1 dose at 7–11 mos, with a 2 <sup>nd</sup> dose at 12–15 mos ≥8 weeks afterwards
12–23 months	0 doses	2 doses ≥8 weeks apart
	1 dose before age 12 mos	2 doses ≥8 weeks apart
	1 dose at ≥12 mos	1 dose ≥8 weeks after most recent dose <sup>2</sup>
	2 or 3 doses <12 mos	1 dose ≥8 weeks after most recent dose <sup>2</sup>
	4 doses of PCV7 or other age-appropriate complete PCV7 schedule	1 PCV13 dose ≥8 weeks after most recent dose <sup>3</sup>
Footnotes		
<sup>1</sup> Minimum interval between doses is 8 weeks except for children vaccinated at age <1 year, for whom minimum interval between doses is 4 weeks.		
<sup>2</sup> No additional PCV13 doses are indicated for children 12–23 months of age who have received 2 or 3 doses of PCV7 <12 months and at least 1 dose of PCV13 at ≥12 months of age.		
<sup>3</sup> For children with underlying medical conditions, a supplemental PCV13 dose is recommended through 71 months of age, depending upon the condition. For a list of conditions see Section III: or MMWR 2010;59:258–61, available at <a href="http://www.cdc.gov/mmwr/PDF/wk/mm5909.pdf">http://www.cdc.gov/mmwr/PDF/wk/mm5909.pdf</a>		

<b>Table 3. Schedules for administering PCV13 to children <math>\geq 24</math> months of age by PCV vaccination history and age</b>		
<b>Age and health status</b>	<b>Total no. of PCV7 plus PCV13 doses received previously</b>	<b>Recommended PCV13 regimen<sup>1</sup></b>
24–59 months, healthy	Unvaccinated or any incomplete schedule <sup>1</sup>	1 dose $\geq 8$ weeks after the most recent dose $< 24$ months of age
	4 doses of PCV7 or other age-appropriate complete PCV7 schedule	1 supplemental dose $\geq 8$ weeks after the most recent dose <sup>2</sup>
24–71 months with underlying medical conditions	Unvaccinated or any incomplete schedule of $< 3$ doses	2 doses, one $\geq 8$ weeks after the most recent dose and another $\geq 8$ weeks later
	Any incomplete schedule of 3 doses	1 dose $\geq 8$ weeks after the most recent dose
	4 doses of PCV7 or other age-appropriate complete PCV7 schedule	1 supplemental dose $\geq 8$ weeks after the most recent dose <sup>2</sup>
$\geq 6$ years with certain high-risk conditions <sup>3</sup>	Regardless of any previously received PCV7 or PPV23 doses	1 supplemental dose PCV 13 now if $\geq 8$ weeks after the most recent PCV dose <sup>2</sup> OR $\geq 1$ year after the last PPV23
<sup>1</sup> A healthy child is considered complete with 1 dose $\geq 24$ months of age. <sup>2</sup> Minimum intervals between PCV doses are 8 weeks. For children who have underlying medical conditions, a supplemental PCV13 dose is recommended through 71 months of age. For a list of conditions see Section III. p 3 of this order. <sup>3</sup> Sickle cell disease, HIV, immunocompromising conditions, cochlear implants, cerebrospinal fluid leaks and functional or anatomic asplenia		

**V. Schedule Algorithm with intervals between doses for pneumococcal vaccine-naïve immunocompromised adults ≥19 years of age.**

**ACIP PCV13 Recommendations for Pneumococcal Vaccine-Naïve Immunocompromised Adults ≥ 19 Years\***

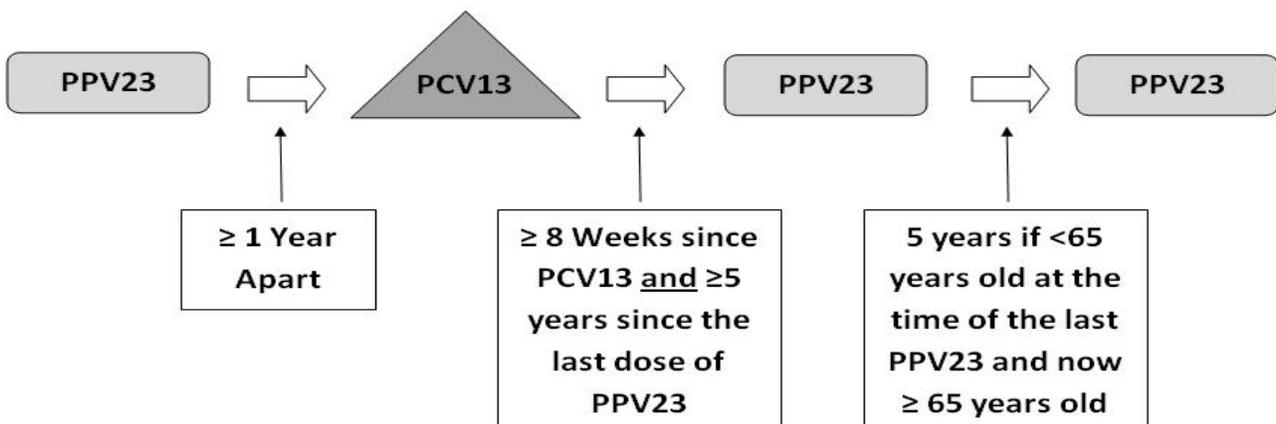


\*See eligible underlying medical conditions noted in Section VII table on pg. 8

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**VI. Schedule Algorithm with intervals between doses for immunocompromised adults ≥19 years\*of age previously vaccinated with PPV23.**

**ACIP PCV13 Recommendations for Immunocompromised Adults ≥ 19 Years\* Previously Vaccinated with PPV23**



\*See eligible underlying medical conditions noted in Section VII table on pg. 8

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<b>VII. Medical conditions or other indications for administration of PCV13 and PPV23 administration and revaccination in children aged 6-18 and adults ≥19 years of age<sup>1</sup></b>				
<b>Risk Group</b>	<b>Underlying Medical condition</b>	<b>PCV-13</b>	<b>PPV-23<sup>2</sup></b>	
		Recommended	Recommended	Revaccination at 5 years
<b>Immunocompetent persons</b>	Chronic heart disease		✓	
	Chronic lung disease		✓	
	Diabetes Mellitus		✓	
	CSF leaks	✓	✓	
	Cochlear implants	✓	✓	
	Alcoholism		✓	
	Chronic liver disease		✓	
	Cigarette smoking		✓	
Persons with functional or anatomic asplenia	Sickle cell disease/other hemaglobinopathies	✓	✓	✓
	Congenital or acquired asplenia	✓	✓	✓
Immunocompromised persons	Congenital or acquired immunodeficiencies	✓	✓	✓
	HIV infection	✓	✓	✓
	Chronic renal failure	✓	✓	✓
	Nephrotic syndrome	✓	✓	✓
	Leukemia	✓	✓	✓
	Lymphoma	✓	✓	✓
	Hodgkin disease	✓	✓	✓
	Generalized malignancy	✓	✓	✓
	Iatrogenic immunosuppression	✓	✓	✓
	Solid organ transplant	✓	✓	✓
	Multiple myeloma	✓	✓	✓

<sup>1</sup> CDC. MMWR 2013;62;25a3 (see Table) <http://www.cdc.gov/mmwr/pdf/wk/mm6225.pdf>

<sup>2</sup> All adults ≥65 years of age should receive a dose of PPV23 regardless of previous vaccination history with pneumococcal vaccine.

<p><b>VIII. CONTRAINDICATIONS</b></p> <p>A. Persons who experienced an anaphylactic reaction to a previous dose of PCV13, PCV7, or any diphtheria toxoid-containing vaccine.</p>	<p><b>IX. PRECAUTIONS</b></p> <p>A. Persons with acute, moderate or severe illnesses with or without fever may choose to delay immunization until symptoms have improved.</p>
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**X. SIDE EFFECTS AND ADVERSE EVENTS**

Reactions to PCV 13 within 7 days of 1 <sup>st</sup> dose	Frequency of Occurrence	
	Any	Severe
Redness at site	24%	0
Swelling at site	20%	0
Tenderness	63%	10%
Fever (39°C →40°C)	38°C: 24%	42°C: 0.1%
Decreased appetite	48%	
Irritability	86%	
Increased sleep	72%	

Reference: package insert, available at:

[www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf](http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf).

## XI. OTHER CONSIDERATIONS

- A. The use of antibiotic prophylaxis in kids under five years of age with functional or anatomical asplenia, and sickle cell disease continues to be recommended. Parents should consult with their treating physician as to whether children who have not experienced invasive pneumococcal disease and have received the recommended pneumococcal immunization should discontinue prophylaxis after 5 years of age.
- B. When an elective splenectomy is performed for any reason, administer PCV13 at least 2 weeks prior to splenectomy. If pneumococcal vaccine is not administered before surgery it should be administered after the procedure as soon as patient's condition is stable. (ACIP General Recommendations on Immunization 1/28/11. Available at: <http://www.cdc.gov/mmwr/pdf/rr/rr6002.pdf> p 22).
- C. Immunization should precede the initiation of immunocompromising therapy by at least two weeks.
- D. 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.
- E. Children with diseases associated with immunosuppressive therapy or radiation therapy and solid organ transplantation may have a diminished response to the vaccine.
- F. For someone with a history of fainting with injections, a 15 minute post immunization observational period is recommended.
- G. The use of pneumococcal conjugate vaccine does not replace the use of 23-valent pneumococcal polysaccharide vaccine (PPV23) in children  $\geq 24$  months of age with sickle cell disease, asplenia, HIV infection, chronic illness or who are otherwise immunocompromised.

## XII. ADVERSE EVENTS REPORTING

Adverse events following immunization should be reported by public providers to the Oregon Health Authority Immunization Program by FAX (971-673-0278) or mail according to state guidelines. Public and private provider reporting forms are available on Standing Orders web page or at <http://1.usa.gov/ImmunizationProviderResources>.

## XIII. REFERENCES

1. CDC. 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), 2013. MMWR 2013; 62; 25a3. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6225a3.htm>
2. 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), 2012. MMWR 2012; 61; 40a4. Available at: [www.cdc.gov/mmwr/preview/mmwrhtml/mm6140a4.htm?s\\_cid=mm6140a4\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6140a4.htm?s_cid=mm6140a4_e)
3. CDC. Licensure of 13-valent pneumococcal conjugate vaccine for adults aged 50 years and older, MMWR 2012, 61; 394–5. Available at: [www.cdc.gov/mmwr/preview/mmwrhtml/mm6121a3.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6121a3.htm)
4. CDC. Invasive pneumococcal disease in young children before licensure of 13-valent pneumococcal conjugate vaccine – United States, 2007. MMWR 2010; 59: 253–61. Available at: [www.cdc.gov/mmwr/PDF/wk/mm5909.pdf](http://www.cdc.gov/mmwr/PDF/wk/mm5909.pdf)
5. Pneumococcal Disease. In: *Epidemiology and Prevention of Vaccine-Preventable Diseases* (“Pink Book”). Atkinson W, Hamborsky J, Wolfe S, eds. 12<sup>th</sup> ed. Washington, DC: Public Health Foundation, 2012: 233–62. Available at: [www.cdc.gov/vaccines/pubs/pinkbook/downloads/pneumo.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/pneumo.pdf)
5. PCV13 (Prevnar®13) 2012 package insert, Available at: [www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf](http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM201669.pdf)

For more information or to clarify any part of the above order, consult with your health officer or call the OHA/ Public Health Division Immunization Program at 971-673-0300 or 711 for TTY.

**To download this order visit our website at**

**<http://1.usa.gov/OregonStandingOrders>**

**To request this material in an alternate format (e.g., braille),**

**Please call 971-673-0300**

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