

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

1. What's New

- A. The 13-valent pneumococcal conjugate vaccine (PCV13) has been deleted from all sections. Previous children and adolescent schedules containing PCV13 have been updated with new recommendations for use of PCV15, PCV20, and PPSV23.
- B. All vaccine schedule tables have been updated to provide additional clarity on recommended subsequent doses, minimum vaccine spacing and the addition of shared clinical decision making, when applicable.
- C. Additional information was provided to clarify what conditions should be considered for patients over the age of 65 to qualify for PCV20 via shared clinical decision making.

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.⁴

3. Vaccine Schedule

A. Routine Schedule

Pneumococcal Vaccine (PCV15 or PCV20, PPSV23) for Persons ≥ 65 Years of Age Dose-0.5-mL, Route varies by product				
Age	Previous PCV Vaccination History	Previous PPSV Vaccination History	Due Now/Route	Due Next
≥ 65 years	Unvaccinated	Unvaccinated	PCV15 IM or	PPSV23 IM or SQ ≥ 1 year later‡
			PCV20 IM	Complete*
	Unvaccinated	1 dose (at any age)	PCV15 IM ≥ 1 year later or	Complete*
			PCV20 IM ≥ 1 year later	Complete*
	PCV13 only (at any age)	Unvaccinated	PCV20 IM ≥ 1 year later or	Complete*
			PPSV23 IM or SQ ≥ 1 year later‡	Complete*
	PCV13 (at any age)	1 dose (at < 65 years old)	PCV20 IM ≥ 5 years after last pneumococcal dose or	Complete*
			PPSV23 IM or SQ ≥ 5 years after last pneumococcal dose‡	

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	PCV13 (at any age)	1 dose (≥ 65 years old)	The patient and vaccine provider may consider administering PCV 20 via shared clinical decision making to patients who have already received PCV13 (but not PCV15 or PCV20) at any age and PPSV23 at or after the age of 65 (See Section 5 for additional details).
‡ For adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak, the minimum interval for PPSV23 is ≥ 8 weeks since last PCV13 dose and ≥ 5 years since last PPSV23 dose; for others, the minimum interval for PPSV23 is ≥ 1 year since last PCV13 dose and ≥ 5 years since last PPSV23 dose.			

B. Special Conditions Schedule

Pneumococcal Vaccine (PCV15 or PCV20; PPSV23) for Persons 7-18 Years of Age with Immunocompromising Conditions* Dose-0.5-mL, Route varies by product					
Acceptable Age Range	Previous PCV Vaccination History	Previous PPSV23 Vaccination History	Due Now/Route (≥ 8 weeks since last pneumococcal vaccine)	Due Next	
7-18 years of age with immune-compromising conditions	No previous history of PCV13, PCV15, or PCV20	Unvaccinated	PCV15 IM <u>or</u>	Administer PPSV23 in ≥8 weeks.	
			PCV20 IM	Complete	
	≥1 dose of PCV13 or PCV15 before age 6	1 dose		PCV15 IM <u>or</u>	Revaccinate with PCV20 or PPSV23 in 5 years.
				PCV20 IM	Complete
	≥1 dose of PCV13 or PCV15 before age 6	Unvaccinated		PCV 20 IM <u>or</u>	Complete
				PPSV23 IM or SQ	Revaccinate with PCV20 or PPSV23 in 5 years.
	≥1 dose of PCV20 before age 6	Unvaccinated	Complete		
	≥1 dose of PCV13 at or after age 6	Unvaccinated		PCV20 IM <u>or</u>	Complete
				PPSV23 IM or SQ	Revaccinate with PCV20 or PPSV23 in 5 years.
		1 dose		PCV20 <u>or</u> †	Complete
			PPSV23†	Complete	
<p>*Children and adolescents on maintenance dialysis, or with immunocompromising conditions such as nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; or sickle cell disease or other hemoglobinopathies</p> <p>†Vaccination must occur at least 8 weeks after the most recent PCV13 dose and at least 5 years after dose 1 PPSV23</p>					

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Pneumococcal Vaccine (PCV15 or PCV20; PPSV23) for Persons 7-18 Years of Age with <u>Chronic Conditions</u>** Dose-0.5-mL, Route varies by product					
Acceptable Age Range	Previous PCV Vaccination History	Previous PPSV23 Vaccination History	Due Now/Route (≥ 8 weeks since last pneumococcal vaccine)	Due Next	
7-18 years of age with chronic conditions	No previous history of PCV13, PCV15, or PCV20	Unvaccinated	PCV15 IM <u>or</u>	Administer PPSV23 in ≥8 weeks.	
			PCV20 IM	Complete	
	≥1 dose of PCV13 or PCV15 before age 6	Unvaccinated	1 dose	PCV15 IM <u>or</u>	Complete
			PCV20 IM	Complete	
	≥1 dose of PCV13 at or after age 6	Unvaccinated	1 dose	PCV 20 IM <u>or</u>	Complete
				PPSV23 IM or SQ	Revaccinate with PCV20 or PPSV23 in 5 years.
	≥1 dose of PCV20 before age 6	Unvaccinated	Complete	Complete	Complete
	≥1 dose of PCV13 at or after age 6	Unvaccinated	1 dose	PCV20 IM <u>or</u>	Complete
			PPSV23 IM or SQ	Complete	
			Complete	Complete	

**Children and adolescents with cerebrospinal fluid leak; chronic heart disease; chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome); chronic liver disease; chronic lung disease (including moderate persistent or severe persistent asthma); cochlear implant; or diabetes mellitus

Pneumococcal Vaccine (PCV15 or PCV20, PPSV23) for Persons 19-64 Years of Age with <u>Immunocompromising Conditions</u>* Dose-0.5-mL, Route varies by product					
Age	Previous PCV Vaccination History	Previous PPSV Vaccination History	Due Now/Route	Due Next	
19-64 years with immune-compromising conditions	Unvaccinated	Unvaccinated	PCV15 IM <u>or</u>	PPSV23 IM or SQ ≥ 8 weeks later‡	
			PCV20 IM	Complete¥	
	Unvaccinated	1 dose	PCV15 IM ≥ 1 year after last PCV dose <u>or</u>	Complete¥	
			PCV20 IM ≥ 1 year after last PCV dose	Complete¥	
	PCV13 only	Unvaccinated	1 dose	PCV20 IM ≥ 1 year after last PCV dose <u>or</u>	Complete¥
				PPSV23 IM or SQ ≥ 8 weeks later‡	Revaccinate with PPSV23 in 5 years.

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	PCV13	1 dose	PCV20 IM ≥ 5 years after last PPSV23 dose <u>or</u> PPSV23 IM or SQ ≥ 5 years after last PPSV23 dose	Complete¥
	PCV13	2 doses	PCV20 IM ≥ 5 years after last PPSV23 dose	Complete¥
<p>* Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiencies, iatrogenic immunosuppression, generalized malignancy, HIV infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, or sickle cell disease or other hemoglobinopathies. ‡May use minimum interval of 8 weeks for adults with an immunocompromising condition*, cochlear implant, or cerebrospinal fluid leak. ¥Review pneumococcal vaccine recommendations when patient turns 65 years old</p>				

Pneumococcal Vaccine (PCV15 or PCV20, PPSV23) for Persons 19-64 Years of Age with <u>Chronic Conditions</u>** Dose-0.5-mL, Route varies by product				
Age	Previous PCV Vaccination History	Previous PPSV Vaccination History	Due Now/Route	Due Next
19-64 years with chronic conditions	Unvaccinated	Unvaccinated	PCV15 IM <u>or</u>	PPSV23 IM or SQ ≥ 1 year later
			PCV20 IM	Complete
	Unvaccinated	1 dose	PCV15 IM ≥ 1 year after last PPSV dose <u>or</u>	Complete
			PCV20 IM ≥ 1 year after last PPSV dose	Complete
	PCV13 only	Unvaccinated	PCV20 IM ≥ 1 year after last PCV dose <u>or</u>	Complete
PPSV23 IM or SQ ≥ 1 year later			Complete¥	
PCV13	1 dose	Complete¥		
<p>**Chronic conditions 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 infection, Hodgkin disease, immunodeficiencies, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplant, or sickle cell disease or other hemoglobinopathies. ¥Review pneumococcal vaccine recommendations when patient turns 65 years old</p>				

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Pneumococcal Vaccine (PCV15 or PCV20, PPSV23) for Persons 19-64 Years of Age with Cochlear Implant or Cerebrospinal Fluid Leak Dose-0.5-mL, Route varies by product				
Age	Previous PCV Vaccination History	Previous PPSV Vaccination History	Due Now/Route	Due Next
19-64 years	Unvaccinated	Unvaccinated	PCV15 IM or	PPSV23 IM or SQ ≥ 8 weeks later‡
			PCV20 IM	Complete
	Unvaccinated	1 dose	PCV15 IM ≥ 1 year after last PPSV dose or	Complete
			PCV20 IM ≥ 1 year after last PPSV dose	Complete
	PCV13 only	Unvaccinated	PCV20 IM ≥ 1 year after last PCV dose or	Complete
			PPSV23 IM or SQ ≥ 8 weeks later‡	Complete¥
PCV13	1 dose	PCV20 IM ≥ 5 years after last pneumococcal dose or	Complete¥	
‡May use minimum interval of 8 weeks for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak. ¥Review pneumococcal vaccine recommendations when patient turns 65 years old				

4. Licensed Vaccines

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
Pneumococcal Conjugate Vaccines				
Pevnar 20™ (PCV20) 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	≥ 6 weeks of age	None
VAXNEUVANCE™ (PCV15) ²		0.5 mL prefilled syringes	≥ 2 months	
Pneumococcal Polysaccharide Vaccine				
Pneumovax 23® (PPSV23) 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

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A. Routine

1. Age 65 years or older:
 - b. 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.
 - c. Previously received only PCV7: follow the recommendation above.
 - d. 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
 - e. 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.
 - f. 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
 - g. 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 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. Individuals living in nursing homes or other long-term care facilities.
- ii. Individuals living in areas with low pediatric pneumococcal conjugate vaccine uptake.

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- iii. Individuals with immunocompromising conditions, cochlear implant, cerebrospinal fluid leak, or more than one of these chronic medical conditions: alcoholism; chronic heart, liver, or lung disease; cigarette smoking; or diabetes.

B. Special Conditions

1. 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:
 - a. Any incomplete series with PCV: no further PCV doses needed
 - b. No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV doses)
- B. Cerebrospinal fluid leak, cochlear implant:
 - a. No history of either PCV or PPSV23: 1 dose PCV, 1 dose PPSV23 at least 8 weeks later
 - b. Any PCV but no PPSV23: 1 dose PPSV23 at least 8 weeks after the most recent dose of PCV
 - c. 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:
 - a. 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)
 - b. 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)
 - c. 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
- D. Hematopoietic Stem Cell Transplant⁶: Children aged <19 years who are hematopoietic stem cell transplant (HSCT) recipients are recommended to receive 4 doses of PCV20, starting 3–6 months after HSCT. Administer 3 doses of PCV20, 4 weeks apart starting 3–6 months after HSCT. Administer a fourth PCV20 dose ≥6 months after the third dose of PCV20 or ≥12 months after HSCT, whichever is later.
 - a. If PCV20 is not available, 3 doses of PCV15 4 weeks apart, followed by a single dose of PPSV23 ≥1 year after HSCT, can be administered. For patients with chronic graft versus host disease (GVHD) who are receiving PCV15, a fourth dose of PCV15 can be administered in place of PPSV23 because these children are less likely to respond to PPSV23. 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)

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- b. A patient's clinical team is best informed to determine the appropriate timing of vaccination.
2. 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
 - c. 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.
 - a) 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
 - b) 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
 - d. Previously received only PCV7: follow the recommendation above
 - e. 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
 - f. 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
 - g. 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

6. Contraindications

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

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

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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 PPSV23.⁴
- B. Lactation: It is not known whether pneumococcal vaccines are excreted in human milk. Use with caution in people who are nursing.¹⁻³
- C. Pregnancy: Pneumococcal vaccine should be considered for persons at increased risk.⁹
- D. Simultaneous administration of PCV15 and PPSV23 is NOT recommended. See section 5, recommendations for use, for the necessary minimum interval between doses.^{4,5}
- E. 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.⁷
- F. 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.⁷
- G. Individuals with diseases associated with immunosuppressive therapy or radiation therapy and solid organ transplantation may have a diminished response to the vaccine.¹⁻³
- H. 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.⁷

9. Side Effects and Adverse Reactions

PCV20¹, PCV15² Adverse Events	Frequency
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).

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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.	
Pneumovax® 23 ³		None	

11. References

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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 65 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>

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- C. Centers for Disease Control and Prevention (CDC). Pneumococcal PneumoRecs VaxAdvisor Mobile App for Vaccine Providers. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. <https://www.cdc.gov/vaccines/vpd/pneumo/hcp/pneumoapp.html>

PROPOSED