

# Pneumococcal 13-valent Conjugate Vaccine (Prevnar 13)

## Criteria for Use

October 2015

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES. The Product Information should be consulted for detailed prescribing information. See the VA National PBM-MAP-VPE Monograph on this drug at [www.pbm.va.gov](http://www.pbm.va.gov) or <http://vaww.pbm.va.gov> for further information.*

**Exclusion Criteria** *If the answer to ANY item below is met, then the patient should NOT receive pneumococcal 13-valent conjugate vaccine.*

- Severe allergic reaction (e.g., anaphylaxis) to any component of pneumococcal 13-valent conjugate vaccine (PCV13) or any diphtheria toxoid-containing vaccine.
- Previously received PCV13 vaccination (Note: PCV13 should be administered only once for all adults)
- Moderate or severe acute illnesses with or without fever (vaccination should be deferred until after the patient improves)

**Inclusion Criteria** *The answers to one of the following must be fulfilled in order to meet criteria.*

- Adults aged  $\geq 65$  years.
- Adults aged  $\geq 19$  years with immunocompromising conditions, functional or anatomic asplenia, cerebrospinal fluid leaks, or cochlear implants (Refer to Table below).

### Dosage and Administration

According to ACIP recommendations, PCV13 should be administered to eligible adults in addition to the 23-valent pneumococcal polysaccharide vaccine (PPSV23). The scheduling of the PCV13 is dependent if the person is pneumococcal vaccine-naïve or has received previous vaccination with PPSV23 as well as the two cohorts stated in the inclusion criteria:

#### **Adults aged $\geq 65$ years.**

**Pneumococcal vaccine-naïve persons.** Immunocompetent adults aged  $\geq 65$  years who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown should receive a dose of PCV13 first, followed by a dose of PPSV23. **The dose of PPSV23 should be given at least 12 months after a dose of PCV13.** If PPSV23 cannot be given during this time window, the dose of PPSV23 should be given during the next visit. The two vaccines should not be coadministered. If a dose of PPSV23 is inadvertently given earlier than the recommended interval, the dose need not be repeated.

**Previous vaccination with PPSV23.** Adults aged  $\geq 65$  years who have previously received  $\geq 1$  doses of PPSV23 also should receive a dose of PCV13 if they have not yet received it. **A dose of PCV13 should be given  $\geq 1$  year after receipt of the most recent PPSV23 dose. For those for whom an additional dose of PPSV23 is indicated, this subsequent PPSV23 dose should be given at least 12 months after PCV13 and  $\geq 5$  years after the most recent dose of PPSV23.**

#### **Adults aged $\geq 19$ years with immunocompromising conditions, functional or anatomic asplenia, cerebrospinal fluid leaks, or cochlear implants (Refer to Table below).**

**Pneumococcal vaccine-naïve persons.** ACIP recommends that adults aged  $\geq 19$  years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, and who have not previously received PCV13 or PPSV23, **should receive a dose of PCV13 first, followed by a dose of PPSV23 at least 8 weeks later.** Subsequent doses of PPSV23 should follow current PPSV23 recommendations for adults at high risk. Specifically, a second PPSV23 dose is recommended 5 years after the first PPSV23 dose for persons aged 19–64 years with functional or anatomic asplenia and for persons with immunocompromising conditions. A second dose of PPSV23 is not recommended for persons 19 through 64 years of age with cochlear implants or CSF leaks. Additionally, those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years, or later if at least 5 years have elapsed since their previous PPSV23 dose.

**Previous vaccination with PPSV23.** Adults aged  $\geq 19$  years with immunocompromising conditions, functional or anatomic asplenia, CSF leaks, or cochlear implants, **who previously have received  $\geq 1$  doses of PPSV23 should be given a PCV13 dose  $\geq 1$  year after the last PPSV23 dose was received. For those who require additional doses of PPSV23, the first such dose should be given no sooner than 8 weeks after PCV13 and at least 5 years after the most recent dose of PPSV23.** As stated above, a second PPSV23 dose is recommended 5 years after the first PPSV23 dose for persons aged 19–64 years with functional or anatomic asplenia and for persons with immunocompromising conditions. Additionally, those who received PPSV23 before age 65 years for any indication should receive another dose of the vaccine at age 65 years, or later if at least 5 years have

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elapsed since their previous PPSV23 dose.

**Table: Administration of PCV13 for adults aged  $\geq 19$  years with immunocompromising conditions, functional or anatomic asplenia, cerebrospinal fluid leaks, or cochlear implants**

Risk group	Underlying medical condition	PCV13	PPSV23	
		Recommended	Recommended	Revaccination 5 yrs after first dose
Immunocompetent persons	Chronic heart disease <sup>†</sup>		✓	
	Chronic lung disease <sup>§</sup>		✓	
	Diabetes mellitus		✓	
	Cerebrospinal fluid leak	✓	✓	
	Cochlear implant	✓	✓	
	Alcoholism		✓	
	Chronic liver disease, cirrhosis		✓	
	Cigarette smoking		✓	
Persons with functional or anatomic asplenia	Sickle cell disease/other hemoglobinopathy	✓	✓	✓
	Congenital or acquired asplenia	✓	✓	✓
Immunocompromised persons	Congenital or acquired immunodeficiency <sup>¶</sup>	✓	✓	✓
	Human immunodeficiency virus infection	✓	✓	✓
	Chronic renal failure	✓	✓	✓
	Nephrotic syndrome	✓	✓	✓
	Leukemia	✓	✓	✓
	Lymphoma	✓	✓	✓
	Hodgkin disease	✓	✓	✓
	Generalized malignancy	✓	✓	✓
	Iatrogenic immunosuppression**	✓	✓	✓
	Solid organ transplant	✓	✓	✓
	Multiple myeloma	✓	✓	✓

\* All adults aged  $\geq 65$  years should receive a dose of PPSV23, regardless of previous history of vaccination with pneumococcal vaccine.

<sup>†</sup> Including congestive heart failure and cardiomyopathies, excluding hypertension.

<sup>§</sup> Including chronic obstructive pulmonary disease, emphysema, and asthma.

<sup>¶</sup> Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).

\*\* Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy.

### Issues for Consideration

- Please note that the PBM CFU follows the current ACIP recommendations for “Use of the 13-valent Pneumococcal Conjugate Vaccine and 23-valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions” (MMWR October 12, 2012; Vol. 61, No 40), “Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged  $\geq 65$  Years” (MMWR September 19, 2014; Vol 63, No 37) and “Intervals between PCV13 and PPSV23 Vaccines” (MMWR September 4, 2015; Vol 64, No 34).
- **For Recipients of Hematopoietic Cell Transplants**, the CDC General Recommendations on Immunization published in 2011 state that “Sequential administration of 3 doses of pneumococcal conjugate vaccine is recommended, beginning 3–6 months after the transplant, followed by a dose of PPSV”. For more information, refer to Tomblyn M, et al. Guidelines for preventing infectious complications among hematopoietic cell transplant recipients: a global perspective. Biol Blood Marrow Transplant 15:1143–1238;2009. Please note that PCV13 has commercially replaced PCV7.
- VHA Clinical Guidance Statement on Pneumococcal Immunization are available on VHA National Center Health Promotion and Disease Prevention (NCP) intranet site [http://vaww.prevention.va.gov/Guidance\\_on\\_Clinical\\_Preventive\\_Services.asp](http://vaww.prevention.va.gov/Guidance_on_Clinical_Preventive_Services.asp)
- Patient information related to the pneumococcal conjugate 13 vaccine is available through CDC.

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