
Medical Policy



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Category: **Medicine**

Title: Pneumococcal Vaccines

**Procedure Code(s):
90669, 90732**

Description/Background

Disease caused by *Streptococcus pneumoniae* (pneumococcus) remains an important cause of morbidity and mortality in the United States, particularly in the very young, the elderly, and persons with certain high-risk conditions. Pneumococcal pneumonia accounts for 10% -25% of all pneumonias and an estimated 40,000 deaths annually. Children less than two years of age, and adults sixty-five years and older, are at highest risk for infection. Recent studies suggest annual rates of bacteremia of 15-19/100,000 for all persons, 50/100,000 for persons greater than or equal to 65 years old, and 160/100,000 for children less than or equal to two years old. In addition, persons of any age with certain underlying medical conditions and those living in special environments are at increased risk for developing a pneumococcal infection. In the pediatric population, pneumococcal infections, which account for the most serious of the bacterial diseases in infancy and early childhood, include acute otitis media, sinusitis, pneumonia, bacterial meningitis, and bacteremia.

There are two types of vaccines available: pneumococcal conjugate vaccine and pneumococcal polysaccharide vaccine for children over age two and adults,

Pneumococcal Conjugate Vaccine:

The pneumococcal vaccines used to immunize adults are capsular polysaccharide vaccines. They are neither immunogenic nor protective in young children, since their immune systems are immature. Therefore, research has focused on the development of additional immunogenic pneumococcal vaccines to provide long-term immunity in children < 2 years of age, who have a high incidence of disease, and poor antibody responses to the capsular polysaccharide vaccine antigens.

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The Food and Drug Administration (FDA) approved the first vaccine to prevent invasive pneumococcal diseases in infants and toddlers < 2 years of age. The vaccine, marketed as Prevnar, is a heptavalent (7-valent) pneumococcal conjugate vaccine that includes seven purified capsular polysaccharides of *S. pneumoniae*, each coupled with a nontoxic variant of CRM 197 (CRM, cross-reactive material). This conjugated vaccine against pneumococcus uses the same technology as the highly successful vaccine against *Haemophilus influenzae* type b. It consists of an immunogenic but inert protein coupled covalently to the polysaccharide coat of the selected strains of pneumococci. The conjugated antigen induces a more powerful, T cell-based immune response in infants, which is developed by the time they are two months of age.

Pneumococcal Polysaccharide Vaccine:

A pneumococcal vaccine was licensed for use in the United States in 1977 consisting of purified capsular antigen from 14 types of *Streptococcus pneumoniae* (1, 2, 3, 4, 6, 8, 9, 12, 14, 19, 23, 25, 51, 56). The 14 types represented in the vaccine were responsible for 68% of bacteremic pneumococcal disease in the United States.

In 1983 a new pneumococcal vaccine was licensed composed of 23 serotypes including all but two (6 and 25) of the original 14 types, and eleven new types (5, 17, 20, 22, 26, 34, 43, 54, 57, 68, 70). These 23 bacterial types are responsible for 87% of bacteremic pneumococcal disease in the United States.

When preparing these polyvalent vaccines, the pneumococcal polysaccharides are extracted and purified separately and then combined in a final product.

CPT/HCPCS Level II Codes and Description

90669	Pneumococcal conjugate vaccine, polyvalent, for children under five years, for intramuscular use
90732	Pneumococcal polysaccharide vaccine, 23-valent, adult or immunosuppressed patient dosage, for use in individuals two years or older, for subcutaneous or intramuscular use

Diagnoses/Medical Conditions

- Pneumococcal meningitis
- Suppurative and unspecified otitis media
- Pneumococcal pneumonia
- Bacteremia

Medical Policy Statement

The safety and effectiveness of pneumococcal conjugate vaccine have been established. It may be considered a useful therapeutic option for children up to five years of age who have not already received the vaccine and are at high risk for serious pneumococcal disease as defined in the American College of Immunization Practices (ACIP) guideline.

The safety and effectiveness of pneumococcal polysaccharide vaccines have been established. It may be considered a useful therapeutic option for patients over age 65, those with chronic illness, and those patients who are immunocompromised.

Rationale

Pneumococcal conjugate vaccine can help prevent serious pneumococcal disease, such as meningitis, bacteremia, and certain ear infections. By preventing the infection, attendant morbidity and mortality can be avoided.

Appropriate administration of pneumococcal polyvalent vaccine may prevent serious disease due to *Streptococcus pneumoniae* in high-risk patients.

Medical Policy Position Summary (Non-clinical summary statement for customer use)

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Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Pneumococcal Conjugate Vaccine:

ACIP recommendations for use pneumococcal conjugate vaccine (PCV7) among infants and children

Children for whom PCV7 is recommended

- All children up to 23 months
- Children aged 24–59 months with the following conditions:
 - Sickle cell disease and other sickle cell hemoglobinopathies, congenital or acquired asplenia, or splenic dysfunction

- Infection with human immunodeficiency virus
- Immunocompromising conditions, including
 - > Congenital immunodeficiencies: B- (humoral) or T-lymphocyte deficiency;
 - > Complement deficiencies, particularly c1, c2, c3, and c4 deficiency; and
 - > Phagocytic disorders, excluding chronic granulomatous disease
 - > Renal failure and nephrotic syndrome
 - > 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

Children for whom PCV7 should be considered:

- All children aged 24–59 months, with priority given to:
 - Children aged 24–35 months
 - Children of Alaska Native or American Indian descent
 - Children of African-American descent
 - Children who attend group day care centers (defined as a setting outside the home where a child regularly spends 4 hours per week with 2 unrelated children under adult supervision)

Pneumococcal Conjugate Vaccine:

CDC recommendations for vaccine use include:

Adults:

- Immunocompetent adults who are at increased risk of pneumococcal disease or its complications because of chronic illnesses (e.g., cardiovascular disease, pulmonary disease, diabetes mellitus, alcoholism, cirrhosis, or cerebrospinal fluid leaks) or who are greater than or equal to 65 years old.
- Immunocompromised adults at increased risk of pneumococcal disease or its complications (e.g., persons with splenic dysfunction or anatomic asplenia, Hodgkin's disease, lymphoma, multiple myeloma, chronic renal failure, nephrotic syndrome, or conditions such as organ transplantation associated with immunosuppression).
- Adults with asymptomatic or symptomatic HIV infection.

Children:

Children greater than or equal to two years of age with chronic illnesses specifically associated with increased risk of pneumococcal disease or its complications (e.g., anatomic or functional asplenia (including sickle cell disease), nephrotic syndrome, cerebrospinal fluid leaks, and conditions associated with immunosuppression).

Table I: Use of Pneumococcal Polysaccharide Vaccine

Immunocompetent Persons	
Who needs pneumococcal polysaccharide vaccine?	Who needs revaccination?
Vaccinate all persons ≥ 65 years of age.	Revaccination is not recommended. However, if a person received a first dose before age 65, give a single revaccination at age 65 if ≥ 5 years have elapsed since the previous dose.
Vaccinate persons who are 2-64 years of age with chronic cardiovascular disease (including congestive heart failure and cardiomyopathies), chronic pulmonary disease (including COPD and emphysema), or diabetes mellitus.	If a person received a first dose before age 65, give a single revaccination at age 65 if ≥ 5 years have elapsed since the previous dose.
Vaccinate persons who are 2-64 years of age with alcoholism, chronic liver disease (including cirrhosis), or cerebrospinal fluid leaks.	If a person received a first dose before age 65, give a single revaccination at age 65 if ≥ 5 years have elapsed since the previous dose.
Vaccinate persons 2-64 years of age with functional or anatomic asplenia (including sickle cell disease and splenectomy).	If patient is >10 years of age, give a single revaccination if ≥ 5 years have elapsed. If patient is ≤ 10 years of age, consider revaccination 3 years later.
Vaccinate persons 2-64 years of age living in special environments or social settings (including Alaska natives and certain American Indian populations).	If a person received a first dose before age 65, give a single revaccination at age 65 if ≥ 5 years have elapsed since the previous dose.
Immunocompromised Persons	
Vaccinate immunocompromised persons ≥ 2 years of age, including those with HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, or nephrotic syndrome; those receiving immunosuppressive therapy (including long-term systemic corticosteroids); and those who have received an organ or bone marrow transplant.	If patient is >10 years of age, give a single revaccination if ≥ 5 years have elapsed. If patient is ≤ 10 years of age, consider revaccination 3 years later.

Adapted from "Prevention of Pneumococcal Disease," *MMWR*, 1997; 46: No.RR-8.

Hyperlink



(Audit criteria)

Related Policies

N/A

Hyperlink



Medicare Information

Effective for services rendered on and after January 1, 1999, HCPCS code 90669 for pneumococcal conjugate vaccine, polyvalent, for intramuscular use is no longer payable through the Medicare program. It is now part of the "Vaccines for Children program." The Vaccines for Children, or VFC, program buys vaccines for children in certain groups who can't afford to buy vaccines. Doctors can get these vaccines for their patients who qualify by joining the VFC program in their state.

Pneumococcal Vaccine (PPV)

- A. The Medicare Part B program covers pneumococcal pneumonia vaccine and its administration when furnished in compliance with any applicable State law by any provider of services or any entity or individual with a supplier number. This includes revaccination of patients at highest risk of pneumococcal infection.

Effective August 14, 2000 Medicare does not require for coverage purposes that the vaccine must be ordered by a doctor of medicine or osteopathy. Therefore, the beneficiary may receive the vaccine without a physician's order and without physician supervision.

- B. Typically, PPV is administered once in a lifetime. Pneumococcal revaccination and its administration are covered by Medicare for patients at high risk of pneumococcal infection.
1. Persons at high risk and those most likely to have rapid declines in antibody levels are those for whom revaccination may be appropriate. This group includes persons with functional or anatomic asplenia (e.g., sickle cell disease, splenectomy), HIV infection leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome, or other conditions associated with immunosuppression such as organ or bone marrow transplantation, and those receiving immunosuppressive chemotherapy. Routine revaccination of people age 65 or older who are not at highest risk is not appropriate.
 2. Revaccinations are covered for beneficiaries that are unsure of their vaccination status. To help avoid potentially unnecessary doses, every patient should be given a record of their vaccination. Nevertheless, those administering the vaccine should not require the patient to present an immunization record before administering the pneumococcal vaccine, nor should they feel compelled to review the patient's complete medical record
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if it is not available. Instead, if the patient is competent, it is acceptable for them to rely on the patient's verbal history to determine prior vaccination status.

- If the patient is uncertain about their vaccination history in the past five years, the vaccine **should** be given.
 - However, if the patient is certain he/she was vaccinated in the last five years, the vaccine **should not** be given.
 - If the patient is certain that the vaccine was given and that more than five years have passed since the previous dose, revaccination is not appropriate **unless** the patient is at highest risk.
3. For any person receiving the vaccine:
- The person's age, health, and vaccination status must be determined.
 - The initial vaccine may be administered only to persons at "high risk" of pneumococcal disease;
 - Revaccination may be administered only to persons at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels, provided that at least five years have passed since receipt of a previous dose of pneumococcal vaccine.
4. Persons at high-risk for whom an initial vaccine may be administered include:
- All people age 65 and older;
 - Immunocompetent adults who are at an increased risk of pneumococcal disease or its complications because of chronic illness (e.g., cardiovascular or pulmonary disease, diabetes mellitus, alcoholism, cirrhosis, or cerebrospinal fluid leaks).
 - Individuals with compromised immune systems (e.g., splenic dysfunction or anatomic asplenia, Hodgkin's disease, lymphoma, multiple myeloma, chronic renal failure, HIV infection, nephrotic syndrome, sickle cell disease, or organ transplantation).

(The above Medicare information is current as of the review date for this policy. However, since Medicare coverage issues and policies may be updated or revised by Centers for Medicare & Medicare Services [CMS, formerly HCFA] on a frequent basis, the most current information may not be contained in this document. For the most current information, you should contact an official source.)

References

- CDC (Centers for Disease Control, "Recommendations of the Immunization Practices Advisory Committee Pneumococcal Polysaccharide Vaccine, MMWR 38(5); 64-68, 73-76, Publication Date: 2/10/89.
- CDC website, "National Immunization Program," Department of Health and Human Services, <<http://www.cdc.gov/nip/vfc/Default.htm>>
- FDA WebSite, US Food and Drug Administration, PRESCRIBING INFORMATION, Pneumococcal7-valent Conjugate Vaccine (Diphtheria CRM,97 Protein), <http://63.75.126.224/Google/fda_search.pl?q=90669&client=fdagov&site=fdagov&searchs_elector=&restrict=&sa=Search>

- Health Care Financing administration, letter to State Health Officials intended to provide detailed guidance regarding coverage of immunization under Title XXI and the Vaccines for Children (VFC) program. Ensuring that all children receive appropriate immunizations is a priority for the President, the First Lady and Secretary Shalala. The unique nature of funding for vaccines create special challenges and options for covering vaccines for CHIP-covered children, <<http://www.hcfa.gov/init/chivfc.htm>>
- Preventing Pneumococcal Disease Among Infants and Young Children; Recommendations of the Advisory Committee on Immunization Practices (ACIP), Continuing Medical Education for U. S. Physicians and Nurses, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Centers for Disease Control and Prevention (CDC), Atlanta, GA 30333, October 6, 2000 / Vol. 49 / No. RR-9, <<http://www.cdc.gov/mmwr/PDF/rr/rr4909.pdf>>
- Winifred S. Hayes, Inc. Hayes Technology Assessment # PNEU 0101.22, "Pneumococcal Conjugate Vaccine for Young Children," effective date May 3, 2000.
- WPS (Wisconsin Physicians' Services), Medicare Part B, National Coverage Provision, SUBJECT: Influenza, Pneumococcal, and Hepatitis-B Vaccinations Replaces: PHYS-040 (WI/IL/MI), INJ 4-5.htm (MN), effective date 10/1/01.

Joint BCBSM/BCN Medical Policy History

Date	Rationale
7/12/02	Joint medical policy established
11/18/03	See comment below

Next Review: This policy is established and is no longer subject to periodic review.

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN 4/13/00	Revised: 6/27/00, 6/28/01
BCBSM N/A	Revised: N/A

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