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The Medical Letter®

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▶ **Capvaxive – A 21-Valent Pneumococcal Conjugate Vaccine**

The FDA has licensed *Capvaxive* (PCV21; Merck), a 21-valent pneumococcal conjugate vaccine, for prevention of invasive pneumococcal disease (IPD) and pneumococcal pneumonia in adults. Four other pneumococcal vaccines are currently available in the US: *Prenvar 20* (PCV20), *Vaxneuvance* (PCV15), and *Prenvar 13* (PCV13) are conjugate vaccines licensed for use in persons ≥ 6 weeks old, and *Pneumovax 23* (PPSV23) is a pneumococcal polysaccharide vaccine licensed for use in persons ≥ 2 years old (see Table 1).¹

Pronunciation and Abbreviation Key

Capvaxive: cap vacks' iv
IPD = invasive pneumococcal disease
PCV = pneumococcal conjugate vaccine
PPSV = pneumococcal polysaccharide vaccine

PNEUMOCOCCAL DISEASE – *Streptococcus pneumoniae* is a common cause of bacterial pneumonia. Adults ≥ 65 years old and persons with certain medical and immunocompromising conditions (see Figure 1 online) are at increased risk of developing IPD. In the US, vaccination against *S. pneumoniae* has substantially reduced the incidence of pneumococcal disease in children and adults.

THE NEW VACCINE – Like PCV13, PCV15, and PCV20, PCV21 contains capsular polysaccharide antigens conjugated to a protein carrier (nontoxic diphtheria CRM₁₉₇ toxin). The 21 serotypes included in *Capvaxive* account for 85% of IPD cases in adults ≥ 65 years old; PCV20 includes serotypes that account for 54% of these cases. PCV21 includes 8 serotypes that are not included in any of the other currently available pneumococcal vaccines (see Table 2); these serotypes account for 30% of IPD cases in adults ≥ 65 years old. Some serotypes included in the other vaccines were excluded from PCV21 because they are no longer commonly associated with pneumococcal disease in adults.

Capvaxive does not protect against serotype 4, which is included in other pneumococcal vaccines and is responsible for $\geq 30\%$ of IPD cases in certain populations (i.e., adults < 65 years old living in some

Key Points: *Capvaxive*

- ▶ **Description:** A 21-valent pneumococcal conjugate vaccine (PCV21).
- ▶ **Indication:** Prevention of invasive pneumococcal disease and pneumococcal pneumonia in adults.
- ▶ **Coverage:** PCV21 includes serotypes that collectively account for 85% of IPD cases in adults ≥ 65 years old.
- ▶ **Adverse Effects:** Injection-site reactions, fatigue, headache, myalgia, and arthralgia.
- ▶ **Dosage:** Single 0.5-mL dose given by intramuscular injection.
- ▶ **Cost:** One dose costs \$287.
- ▶ **Conclusion:** The CDC Advisory Committee on Immunization Practices (ACIP) recommends PCV21 as an option for adults when a PCV vaccine is recommended.

western US regions who are homeless, have chronic lung disease or alcohol use disorder, smoke, or use injectable drugs).

CLINICAL STUDIES – FDA approval of *Capvaxive* was based on the results of 3 trials (STRIDE-3, STRIDE-5, and STRIDE-6; STRIDE-5 is unpublished) evaluating its immunogenicity in both vaccine-naive and previously vaccinated adults. In STRIDE-3 and STRIDE-6, immune responses elicited by PCV21 were noninferior to those elicited by PCV15, PCV20, and PPSV23 for all shared serotypes.^{2,3}

In STRIDE-5 (summarized in the package insert), 1080 adults ≥ 50 years old were randomized to receive PCV21 with or 30 days after receiving a quadrivalent

Table 1. Pneumococcal Conjugate Vaccines

Vaccine	Formulations	Usual Adult Dosage	Cost ¹
<i>Prenvar 13</i> (PCV13; Pfizer)	0.5 mL susp in single-use prefilled syringes	0.5 mL x 1 dose	\$211.10
<i>Vaxneuvance</i> (PCV15; Merck)	0.5 mL susp in single-use prefilled syringes	0.5 mL x 1 dose	215.30
<i>Prenvar 20</i> (PCV20; Pfizer)	0.5 mL susp in single-use prefilled syringes	0.5 mL x 1 dose	232.20
<i>Capvaxive</i> (PCV21; Merck)	0.5 mL soln in single-use prefilled syringes	0.5 mL x 1 dose	287.00

soln = solution; susp = suspension

1. Approximate WAC for one dose. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. September 5, 2024. Reprinted with permission by First Databank, Inc. All rights reserved. ©2024. www.fdbhealth.com/drug-pricing-policy.

Table 2. Pneumococcal Vaccine Serotypes

Serotype	PCV13	PCV15	PCV20	PPSV23	PCV21
1	X	X	X	X	
3	X	X	X	X	X
4	X	X	X	X	
5	X	X	X	X	
6A	X	X	X		X
6B	X	X	X	X	
7F	X	X	X	X	X
9V	X	X	X	X	
14	X	X	X	X	
18C	X	X	X	X	
19A	X	X	X	X	X
19F	X	X	X	X	
23F	X	X	X	X	
22F		X	X	X	X
33F		X	X	X	X
8			X	X	X
10A			X	X	X
11A			X	X	X
12F			X	X	X
15B			X	X	X
2				X	
9N				X	X
17F				X	X
20				X	
15A					X
15C					X ¹
16F					X
20A					X
23A					X
23B					X
24F					X
31					X
35B					X

PCV13 = 13-valent conjugate vaccine (*Prenvar 13*); PCV15 = 15-valent conjugate vaccine (*Vaxneuvance*); PCV20 = 20-valent conjugate vaccine (*Prenvar 20*); PPSV23 = 23-valent polysaccharide vaccine (*Pneumovax 23*); PCV21 = 21-valent conjugate vaccine (*Capvaxive*).

1. *Capvaxive* contains the de-O-acetylated polysaccharide of 15B, which induces immunogenicity to serotype 15C due to a similar molecular structure.

influenza vaccine. Immune responses elicited when the two vaccines were administered together were noninferior to those elicited when PCV21 was given 30 days after influenza vaccination for 20 of 21 pneumococcal serotypes (not serotype 23B) and for 3 of 4 influenza strains.

ADVERSE EFFECTS – Injection-site reactions (pain, swelling, and erythema), fatigue, headache, myalgia, and arthralgia were the most common adverse effects reported with *Capvaxive* in clinical trials. Adverse effects were similar when *Capvaxive* was administered alone or with a quadrivalent inactivated influenza vaccine. Like other conjugate vaccines, *Capvaxive* is contraindicated for use in persons with a severe allergy to diphtheria toxoid.

PREGNANCY – The American College of Obstetricians and Gynecologists (ACOG) recommends pneumococcal vaccination for pregnant women at increased risk of severe pneumococcal disease.⁴ No adequate data are available on the use of PCV21 in pregnant women. No adverse developmental outcomes were observed in animal studies.

ACIP RECOMMENDATIONS – The CDC Advisory Committee on Immunization Practices (ACIP) recommends PCV21 as an option for adults who are candidates for pneumococcal vaccination.⁵ Previously unvaccinated adults who are ≥ 65 years old or 19-64 years old with certain underlying medical conditions or other risk factors should receive a one-time dose of PCV21 or PCV20, or a dose of PCV15 followed ≥ 1 year later by PPSV23.

Specific recommendations for pneumococcal vaccination of adults based on vaccination status, age, and risk factors are available in Figures 1 and 2 (online).

DOSAGE AND ADMINISTRATION – *Capvaxive* is supplied in single-dose, prefilled syringes that should be stored in a refrigerator. It should be given intramuscularly as a single 0.5-mL dose.

CONCLUSION – The new 21-valent pneumococcal conjugate vaccine *Capvaxive* contains serotypes that collectively account for 85% of invasive pneumococcal disease in older adults in the US, including 8 serotypes that are not included in other currently available pneumococcal vaccines. It is a recommended option for adults who are candidates for pneumococcal vaccination. ■

Additional Content Available Online

Figure 1: Pneumococcal Vaccine Recommendations for Adults 19-64 Years Old

<http://medicalletter.org/TML-article-1713f>

Figure 2: Pneumococcal Vaccine Recommendations for Adults ≥ 65 Years Old

<http://medicalletter.org/TML-article-1713g>

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