Disparities still exist in vaccinating infants against IPD in the US[1]

Vaxneuvance® Pneumococcal 15-valent Conjugate Vaccine

VAXNEUVANCE is given as a 4-dose series. Despite this, some babies do not receive the 4th dose of the PCV series.[1,a-e]

1/16 **COMMERCIALLY INSURED** babies received their third dose but not their fourth dose

1/8 **MEDICAID-ELIGIBLE** babies received their third dose but not their fourth dose

1/4 **UNINSURED** babies received their third dose but not their fourth dose

On average, for babies born between 2010-2016,

~25.5%

of babies below the poverty level did not receive their 4th dose of a PCV by 24 months.[2]

[a]The primary series consists of 3 doses routinely given at 2, 4, and 6 months of age. The minimum interval between doses given to infants is 4 weeks.
[b]The first dose can be administered as early as 6 weeks of age.
[c]The fourth dose should be administered at approximately 12–15 months of age and at least 2 months after the third dose.
[d]NIS-Child, a random digit-dialed telephone survey of parents/guardians of children born in 2019 and 2020, aged 19–35 months. The survey results were used by the CDC to estimate vaccination coverage with ACIP-recommended vaccines in the United States.[1]
[e]Children's health insurance status was reported by a parent or guardian. The insured population includes private insurance, Medicaid, and other insurance types.[1]

ACIP, Advisory Committee on Immunization Practices; CDC, Centers for Disease Control and Prevention; IPD, invasive pneumococcal disease; NIS-Child, National Immunization Survey – Child; PCV, pneumococcal conjugate vaccine.

Indications and Usage

VAXNEUVANCE is indicated for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 6 weeks of age and older.

Select Safety Information

Do not administer VAXNEUVANCE to individuals with a severe allergic reaction (eg, anaphylaxis) to any component of VAXNEUVANCE or to diphtheria toxoid.

Some individuals with altered immunocompetence, including those receiving immunosuppressive therapy, may have a reduced immune response to VAXNEUVANCE.

Apnea following intramuscular vaccination has been observed in some infants born prematurely. Vaccination of premature infants should be based on the infant's medical status and the potential benefits and possible risks.

(Select Safety Information continues on the next page)

VAXNEUVANCE demonstrated robust immunogenicity, including coverage for key disease-causing Serotypes 3, 22F, and 33F[3,4,a]

Vaxneuvance®
Pneumococcal 15-valent
Conjugate Vaccine

Immune responses for VAXNEUVANCE against 15 serotypes postdose 3 and postdose 4[a]

	Immune Responses[5]	Comparable to PCV13	Superior to PCV13
First Year of Life	Postdose 3 (primary series) **IgG response rates**[5]	12 shared serotypes	Shared Serotype 3 Unique Serotypes 22F and 33F
	Postdose 3 (primary series) **IgG GMC ratios**[5]	11 shared serotypes*	Shared Serotype 3 Unique Serotypes 22F and 33F
	Postdose 4 (booster dose) **IgG GMC ratios**[5]	12 shared serotypes	Shared Serotype 3 Unique Serotypes 22F and 33F

Randomized controlled trials assessing the clinical efficacy of VAXNEUVANCE compared to PCV13 have not been conducted.

***Additional information about postdose 3 IgG GMC ratios:** The serotype-specific IgG GMC for 6A at the postdose 3 measurement for VAXNEUVANCE missed noninferiority to PCV13 by a small margin (2-sided 95% CI lower bound of GMC ratio [VAXNEUVANCE/PCV13] was 0.48, with noninferiority criterion of >0.5).

Study Design

Study 8 was a pivotal, double-blind, active comparator-controlled study in which participants were randomized to receive VAXNEUVANCE (N=860) or PCV13 (N=860) in a 4-dose series. The first 3 doses were administered to infants at 2, 4, and 6 months of age and the fourth dose was administered to children at 12 through 15 months of age. Participants also received other licensed pediatric vaccines concomitantly. Immune responses were measured by IgG response rates, IgG GMCs, and OPA GMTs for all 15 serotypes contained in VAXNEUVANCE.

[a]Measurements were taken 1 month postdose 3 and 4.

CI, confidence interval; GMC, geometric mean concentration (mcg/mL); GMT, geometric mean titer; IgG, Immunoglobulin G; OPA, opsonophagocytic activity; PCV13, 13-valent pneumococcal conjugate vaccine.

Select Safety Information *(continued)*

The most commonly reported solicited adverse reactions in children vaccinated at 2, 4, 6, and 12 through 15 months of age, provided as a range across the 4-dose series, were: irritability (57.3% to 63.4%), somnolence (24.2% to 47.5%), injection-site pain (25.9% to 40.3%), fever ≥38.0°C (13.3% to 20.4%), decreased appetite (14.1% to 19.0%), injection-site induration (13.2% to 15.4%), injection-site erythema (13.7% to 21.4%), and injection-site swelling (11.3% to 13.4%).

The most commonly reported solicited adverse reactions in children 2 through 17 years of age vaccinated with a single dose were: injection-site pain (54.8%), myalgia (23.7%), injection-site swelling (20.9%), injection-site erythema (19.2%), fatigue (15.8%), headache (11.9%), and injection-site induration (6.8%).

Vaccination with VAXNEUVANCE may not protect all vaccine recipients.

VAXNEUVANCE provided superior immune responses for Serotype 3 vs PCV13

Vaxneuvance® Pneumococcal 15-valent Conjugate Vaccine

In 2010, PCV13 introduced routine pediatric coverage against Serotype 3.[6,7] In a pooled analysis from 2018-2021, Serotype 3 was a leading cause of IPD in children younger than 5 years old.[4,a,b]

Superior IgG response rate for shared Serotype 3 compared to PCV13

Postdose 3 (primary series)

93.1% VAXNEUVANCE

74% PCV13

IgG response rate percentage point difference (VAXNEUVANCE-PCV13), 19.1 (95% CI: 14.4, 24.0).

Superior IgG GMC Ratios for shared Serotype 3 compared to PCV13

Postdose 3 (primary series)

↑ 70% higher immunogenicity vs PCV13

IgG GMC Ratio vs PCV13, 1.70 (95% CI: 1.54, 1.86).

Postdose 4 (booster dose)

↑ 43% higher immunogenicity vs PCV13

IgG GMC Ratio vs PCV13, 1.43 (95% CI: 1.30, 1.57).

Randomized controlled trials assessing the clinical efficacy of VAXNEUVANCE compared to PCV13 have not been conducted.

[a]From 2018-2021, the top 6 IPD-causing serotypes in children under 5 years were 15C, 33F, 19F, 3, 23B, and 22F. Serotypes 15C and 23B are not included in any pediatric PCV in the US.[4,7-9]
[b]The CDC noted that historic decreases of IPD burden in 2020 were likely due to the associated mitigation measures implemented during the COVID-19 pandemic, as documented by the Active Bacterial Core (ABC) surveillance data.[10]

CDC, Centers for Disease Control and Prevention; CI, confidence interval; GMC, geometric mean concentration (mcg/mL); IgG, Immunoglobulin G; IPD, invasive pneumococcal disease; PCV, pneumococcal conjugate vaccine; PCV13, 13-valent pneumococcal conjugate vaccine.

Select Safety Information *(continued)*

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(Select Safety Information continues on the next page)

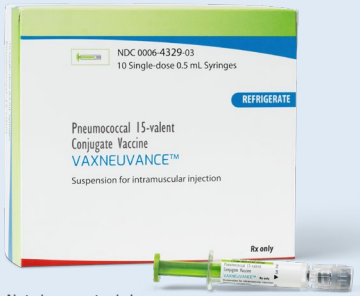
VAXNEUVANCE helps protect against pediatric invasive pneumococcal disease, including in the first year of life

Vaxneuvance®
Pneumococcal 15-valent Conjugate Vaccine

VAXNEUVANCE is CDC, AAP, and AAFP recommended as an option for your pediatric patients and is given as a four-dose series.[5,11-13]

Indications and Usage

VAXNEUVANCE is indicated for active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F in individuals 6 weeks of age and older.



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Vaccinate with VAXNEUVANCE today.

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AAP, American Academy of Pediatrics; AAFP, American Academy of Family Physicians; CDC, Centers for Disease Control and Prevention.

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Select Safety Information *(continued)*

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The most commonly reported solicited adverse reactions in children 2 through 17 years of age vaccinated with a single dose were: injection-site pain (54.8%), myalgia (23.7%), injection-site swelling (20.9%), injection-site erythema (19.2%), fatigue (15.8%), headache (11.9%), and injection-site induration (6.8%).

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Before administering VAXNEUVANCE, please read the accompanying Prescribing Information. The Patient Information also is available.
For additional copies of the Prescribing Information, please call 800-672-6372, visit MerckVaccines.com,® or contact your Merck representative.