CAPVAXIVE™
Pneumococcal 21-valent Conjugate Vaccine

A PCV SPECIFICALLY FOR ADULTS THAT HELPS PROTECT AGAINST THE SEROTYPES THAT ARE RESPONSIBLE FOR THE MOST CASES OF ADULT IPD AT A NATIONAL LEVEL[1-3,a,b]

Pneumococcal pneumonia and IPD are serious risks for your adult patients[2,4-6]

Pneumococcal pneumonia is the most common clinical manifestation of pneumococcal disease in adults, accounting for **~150,000 annual hospitalizations** and **10%–30% of all adult CAP cases** in the United States.[7]

When pneumococcal bacteria invade normally sterile sites in the body, this is referred to as **IPD** and **can lead to hospitalization and complications.**[7]

Although IPD can affect anyone, the risk increases with age[8,a]

Individuals aged ≥50 years have

~4× Increased risk for IPD

compared with adults aged 18–49 years

The serotypes that cause the majority of IPD cases in US adults have shifted over time[2]

Nearly half (~48%) of all IPD cases in adults aged ≥50 years, at a national level, are caused by serotypes not included in any other PCV approved for adults[1-3,a,b]

These values are based on CDC epidemiologic data and do not reflect the efficacy of any pneumococcal vaccines.[2]

[a]Based on CDC ABC surveillance data from the years 2018 to 2022, representing ~35 million persons and 10 states across the US. Regional variations may exist.[2,8,9]
[b]Other approved PCVs include PCV13, PCV15, and PCV20.[2]

The CDC recommends 1 Dose of CAPVAXIVE for[14-16]:

Adults aged ≥50 years:
- Vaccine-naïve or vaccination history is unknown *(lowered from ≥65 years)*

Adults aged 19–49 years:
- With certain chronic medical conditions or other risk factors who are vaccine-naïve or vaccination history is unknown
  - Diabetes, renal disorders, chronic heart disease, chronic liver disease, chronic lung disease including asthma, smoking, alcoholism

Previously Vaccinated Adults:
- For adults ≥19 years of age:
  - Previously vaccinated with PCV13 only or PPSV23 only, ≥1 year prior at any age
  - Previously vaccinated but have not completed a recommended series[c]
- For adults ≥65 years of age:
  - As a supplemental dose for those previously vaccinated with PCV13 and PPSV23*

*Routine if PCV13 was administered at any age and PPSV23 was administered before age 65 with the last pneumococcal vaccine being at least 5 years prior. Shared clinical decision-making if PCV13 was administered at any age and PPSV23 was administered at or after the age of 65 and the last pneumococcal vaccine was at least 5 years prior.

[c]Patients are eligible to receive CAPVAXIVE if they only received PCV13 or PPSV23 ≥1 year ago or if the last dose of PPSV23 was completed ≥5 years ago where PCV13 and PPSV23 were both received.[14,15]

Indications and Usage

CAPVAXIVE™ is indicated for:

- active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.
- active immunization for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.

The indication for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Select Safety Information

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

Individuals with altered immunocompetence, including those receiving immunosuppressive therapy, may have a reduced immune response to CAPVAXIVE.

The most commonly reported (>10%) solicited adverse reactions in individuals 18 through 49 years of age who received CAPVAXIVE were: injection-site pain (73.1%), fatigue (36.0%), headache (27.5%), myalgia (16.4%), injection-site erythema (13.8%), and injection-site swelling (13.3%).

The most commonly reported (>10%) solicited adverse reactions in individuals 50 years of age and older who received CAPVAXIVE were: injection-site pain (41.2%), fatigue (19.7%), and headache (11.0%).

Vaccination with CAPVAXIVE may not protect all vaccine recipients.

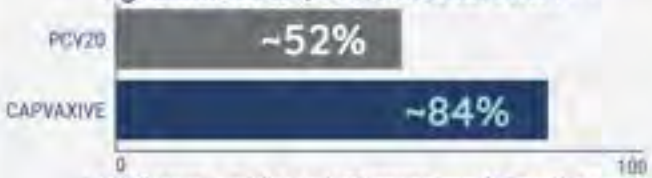
ABC, Active Bacterial Core; CAP, community-acquired pneumonia; CDC, Centers for Disease Control and Prevention; IPD, invasive pneumococcal disease; PCV, pneumococcal conjugate vaccine; PCV13, 13-valent pneumococcal conjugate vaccine; PCV15, 15-valent pneumococcal conjugate vaccine; PCV20, 20-valent pneumococcal conjugate vaccine; PPSV23, 23-valent pneumococcal polysaccharide vaccine; US, United States.

Indication and Select Safety Information continued on the following page

CAPVAXIVE™
Pneumococcal 21-valent Conjugate Vaccine

A DESIGN THAT HELPS TO ADDRESS TRENDS IN ADULT IPD EPIDEMIOLOGY[1,3]

Percentage of IPD Cases Caused by Serotypes Covered by CAPVAXIVE vs PCV20 Among Adults Aged ≥50 Years, at a National Level[1-3,a]



% of IPD cases in adults aged ≥50 years **covered by vaccine serotypes**

Based on CDC ABC surveillance data from the years 2018–2022, representing ~35 million persons and 10 states across the US. Regional variations may exist.[1,3]

- The serotypes covered by CAPVAXIVE that are not covered by PCV20 contribute to ~38% of IPD cases in adults aged ≥50 years.[1-3]
- The serotypes covered by PCV20 that are not covered by CAPVAXIVE make up ~7% of IPD cases in adults aged ≥50 years.[1-3]

These values are based on CDC epidemiologic data and do not reflect the efficacy of the respective vaccines.[2] There are currently no studies comparing the efficacy of CAPVAXIVE and PCV20.

In certain at-risk populations in Alaska, Colorado, New Mexico, Oregon, and the Navajo Nation, a higher prevalence of IPD caused by serotype 4, which is not included in CAPVAXIVE, has been reported. IPD surveillance from other geographic areas in the US has not detected significant percentages of serotype 4.[1,3]

[a]PCV20 serotypes for IPD case coverage: 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F.[1,3] CAPVAXIVE serotypes for IPD case coverage: 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B.

As a pharmacist, you are uniquely positioned to identify appropriate patients who may benefit from vaccination.[10-20]

- Pharmacists play a vital role in promoting the **importance of vaccinations for public health.**[17]
- US community pharmacies are **highly accessible and particularly successful at reaching rural patients**, who may otherwise be out of reach to HCPs.[19]

Pharmacy encounters are additional opportunities to **help educate patients and increase their awareness** of the risk for pneumococcal pneumonia and IPD as well as available vaccines.[18,21,22]

Indications and Usage

CAPVAXIVE™ is indicated for:

- active immunization for the prevention of invasive disease caused by *Streptococcus pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.
- active immunization for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.

The indication for the prevention of pneumonia caused by *S. pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Select Safety Information

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

Individuals with altered immunocompetence, including those receiving immunosuppressive therapy, may have a reduced immune response to CAPVAXIVE.

Before administering CAPVAXIVE, 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.

To learn more, visit WWW.CAPVAXIVEHCP.COM

ABC, Active Bacterial Core; CDC, Centers for Disease Control and Prevention; HCPs, health care providers; IPD, invasive pneumococcal disease; PCV20, 20-valent pneumococcal conjugate vaccine; US, United States.

References

1. Data available on request from Merck & Co., Inc., Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package US-PVV-00504. **2.** ABCs bact facts interactive data dashboard. SPN serotypes 1998-2022. Centers for Disease Control and Prevention. Last Updated August 28, 2024. Accessed September 25, 2024. https://www.cdc.gov/abcs/bact-facts/data-dashboard.html **3.** 1998/2022 serotype data for invasive pneumococcal disease cases by age group from Active Bacterial Core surveillance, ages 18-49, 50-64, ≥65 plus, year is between 2018 and 2022. Centers for Disease Control and Prevention. Last updated July 22, 2024. Accessed August 14, 2024. https://data.cdc.gov/Public-Health-Surveillance/1998-2022-Serotype-Data-for-Invasive-Pneumococcal-/qvzb-qs6p/data **4.** Grant LR, et al. *Open Forum Infect Dis*. 2023;10(5):ofad192. doi: 10.1093/ofid/ofad192 **5.** Grant LR, et al. Supplementary material. *Open Forum Infect Dis*. 2023;10(5):ofad192. doi: 10.1093/ofid/ofad192 **6.** Clinical features of pneumococcal disease. Centers for Disease Control and Prevention. February 6, 2024. Accessed May 21, 2024. https://www.cdc.gov/pneumococcal/hcp/clinical-signs/ **7.** Gierke R, et al. Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book). 14th edition. Chapter 17: Pneumococcal disease. Centers for Disease Control and Prevention. May 1, 2024. Accessed July 23, 2024. https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-17-pneumococcal-disease.html **8.** Data available on request from Merck & Co., Inc., WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package US-PVV-00516. **9.** Active Bacterial Core surveillance (ABCs) report, Emerging Infections Program network, *Streptococcus pneumoniae*, 2018. Centers for Disease Control and Prevention. Updated May 22, 2020. Accessed June 14, 2024. https://stacks.cdc.gov/view/cdc/140450 **10.** Active Bacterial Core surveillance (ABCs) report. Emerging Infections Program network, *Streptococcus pneumoniae*, 2019. Centers for Disease Control and Prevention. Updated June 16, 2021. Accessed January 4, 2024. https://www.cdc.gov/abcs/downloads/SPN_Surveillance_Report_2019.pdf **11.** Active Bacterial Core Surveillance (ABCs) Report. Emerging Infections Program Network, *Streptococcus pneumoniae*, 2020. Centers for Disease Control and Prevention. Updated September 20, 2022. Accessed October 15, 2024. https://stacks.cdc.gov/view/cdc/140328 **12.** Active Bacterial Core surveillance (ABCs) report. Emerging Infections Program network, *Streptococcus pneumoniae*, 2021. Centers for Disease Control and Prevention. Updated June 2, 2023. Accessed January 4, 2024. https://www.cdc.gov/abcs/downloads/SPN_Surveillance_Report_2021.pdf **13.** Active Bacterial Core surveillance (ABCs) report, Emerging Infections Program network, *Streptococcus pneumoniae*, 2022. Centers for Disease Control and Prevention. Updated July 5, 2024. Accessed September 4, 2024. https://www.cdc.gov/abcs/downloads/SPN_Surveillance_Report_2022.pdf **14.** Kobayashi M, et al. Use of 21-valent pneumococcal conjugate vaccine among U.S. adults: recommendations of the Advisory Committee on Immunization Practices — United States, 2024. *MMWR Morb Mortal Wkly Rep*. 2024;73(36):793-798. doi:10.15585/mmwr.mm7336a3 **15.** Kobayashi M. Summary of work group interpretation of EtR and policy options: PCV use in adults aged ≥50 years. Slide deck presented at: Advisory Committee on Immunization Practices Meeting; October 23, 2024; Atlanta, GA. Accessed October 23, 2024. https://www.cdc.gov/acip/downloads/slides-2024-10-23-24/04-Kobayashi-Pneumococcal-508.pdf **16.** ACIP recommendations. Centers for Disease Control and Prevention. August 29, 2024. Accessed October 25, 2024. https://www.cdc.gov/acip/vaccine-recommendations/ **17.** Prevnar 20. Prescribing Information. Pfizer Inc; 2023. **18.** Cameron G, et al. ASHP Statement on the Pharmacist's Role in Public Health. *Am J Health Syst Pharm*. 2022;79(5):388-399. doi:10.1093/ajhp/zxab338 **19.** Bereebrok LA, et al. Access to community pharmacies: A nationwide geographic information systems cross-sectional analysis. *J Am Pharm Assoc (2003)*. 2022;62(6):1816–1822.e2. doi:10.1016/j.japh.2022.07.003 **20.** Valliant SN, et al. Pharmacists as accessible health care providers: quantifying the opportunity. *J Manag Care Spec Pharm*. 2022;28(1):85–90. doi:10.18553/jmcp.2022.28.1.85 **21.** Strategies for increasing adult vaccination rates. Centers for Disease Control and Prevention. Last reviewed August 9, 2024. Accessed October 30, 2024. https://www.cdc.gov/vaccines-adults/hcp/vaccination-guidelines/index.html **22.** Vaccination programs: general best practice guidelines for immunization. Centers for Disease Control and Prevention. Updated July 12, 2017. Accessed April 9, 2024. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/programs.html

MERCK