

To: NGPG Providers
 From: Alix Schnibben, PharmD, BCACP, CTTS
 Director, Clinical Quality and Ambulatory Pharmacy Services
 Re: **Pevnar 20™ (Pneumococcal 20-valent Conjugate Vaccine) Formulary Information**

Dear NGPG Providers:

I am pleased to share that Northeast Georgia Physicians Group has placed Pevnar 20™ (Pneumococcal 20-valent Conjugate Vaccine) on formulary. Approved by the US Food and Drug Administration (FDA) on June 8, 2021, Pevnar 20 is indicated for the prevention of invasive pneumococcal disease and pneumococcal pneumonia in adults. The indication for the prevention of pneumonia caused by *S. pneumoniae* serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA) assay. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.¹

Pevnar 20 delivers the most serotypes in a pneumococcal conjugate vaccine by adding 7 serotypes to Pevnar 13 (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM₁₉₇ Protein]).¹⁻³ Pevnar 13 and Pevnar 20 are the only conjugate vaccines that are FDA-approved for the prevention of pneumococcal pneumonia.^{1-3*}

On October 20, 2021, the CDC’s Advisory Committee on Immunization Practices (ACIP) voted to revise its adult pneumococcal vaccination recommendations.

ACIP adult pneumococcal vaccination recommendations

Aged 65 years or older	Vaccination recommendations
Adults who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown	Pevnar 20 OR PCV15 followed by PPSV23
Aged 19 to 64 years old	Vaccination recommendations
Adults with certain underlying medical conditions or other risk factors* who have not previously received a pneumococcal conjugate vaccine or whose previous vaccination history is unknown	Pevnar 20 OR PCV15 followed by PPSV23

*Alcoholism, chronic heart/liver/lung disease, cigarette smoking, diabetes mellitus, chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease or other hemoglobinopathies, CSF leak, or cochlear implant.

CDC = Centers for Disease Control and Prevention; CSF = cerebrospinal fluid; PCV15 = pneumococcal 15-valent conjugate vaccine; PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

As a healthcare provider, you play a vital role in educating your adult patients. The Centers for Disease Control and Prevention recommends that all healthcare providers assess immunization status of all patients at every visit and recommend vaccines that patients need. **Your recommendation can help make a difference.**⁵

For more information about Prevnar 20 and Prevnar 13, including full Prescribing Information for both, please see the hyperlinks at the bottom of this letter.

IMPORTANT SAFETY INFORMATION AND INDICATIONS

IMPORTANT SAFETY INFORMATION

- Severe allergic reaction (e.g., anaphylaxis) to any component of Prevnar 20, Prevnar 13, or to diphtheria toxoid is a contraindication
- Safety and immunogenicity data on Prevnar 20 are not available for individuals in immunocompromised groups and vaccination should be considered on an individual basis. Based on experience with pneumococcal vaccines, individuals with altered immunocompetence may have reduced immune responses to Prevnar 20
- Immunocompromised individuals or individuals with impaired immune responsiveness due to the use of immunosuppressive therapy may have reduced antibody response to Prevnar 13
- For Prevnar 20, in adults 18 years of age and older, the most commonly reported solicited adverse reactions (>10%) were pain at the injection site, muscle pain, fatigue, headache, and arthralgia. Additionally, injection site swelling was also reported (>10%) in adults 18 through 59 years of age
- For Prevnar 13, in adults 18 years of age and older, the most commonly reported solicited adverse reactions (>5%) were pain, redness, and swelling at the injection site, limitation of arm movement, fatigue, headache, muscle pain, joint pain, decreased appetite, vomiting, fever, chills, and rash

INDICATIONS

- Prevnar 20 is indicated for active immunization for the prevention of pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older
- The indication of Prevnar 20 for the prevention of pneumonia caused by *S. pneumoniae* serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA) assay. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial
- Prevnar 13 is indicated for active immunization for the prevention of pneumonia and invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F in adults 18 years of age and older

Prevnar 13® (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM₁₉₇ Protein]) Limitations of Use:

Prevnar 13 will only help protect against *S. pneumoniae* serotypes in the vaccine

Sincerely,

Alix Schnibben, PharmD, BCACP, CTS



Northeast Georgia

PHYSICIANS GROUP

Please click for [Pevnar 20](#) and [Pevnar 13](#) full Prescribing Information. Pevnar 20 full Prescribing Information is also available at <https://prevnar20.pfizerpro.com/>.

Pevnar 13 full Prescribing Information is also available at <https://www1.pfizerpro.com/product/prevnar-13/adult>

1. Pevnar 20 Prescribing Information, Wyeth Pharmaceuticals LLC, 2021. 2. Pevnar 13® Prescribing Information, Wyeth Pharmaceuticals LLC, 2019. 3. Vaxneuvance™ (pneumococcal 15-valent conjugate vaccine) Prescribing Information. Whitehouse Station, NJ: Merck. July 2021. Accessed September 15, 2021. <https://www.fda.gov/media/150819/download>
2. Kobayashi M. National Center for Immunization and Respiratory Diseases. October 20, 2021. Accessed October 21, 2021. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/02-Pneumococcal-Kobayashi-508.pdf>
3. Centers for Disease Control and Prevention. Standards for practice: vaccine recommendation. Updated May 2, 2016. Accessed September 21, 2021. <https://www.cdc.gov/vaccines/hcp/adults/for-practice/standards/recommend.html>.