From: dph.immunizations@ct.gov <noreply@everbridge.net>
Sent: Tuesday, August 15, 2023 1:19 PM
Subject: Advisory Committee on Immunization Practices (ACIP) Updates

DEPARTMENT OF PUBLIC HEALTH

August 15, 2023

This communication is being sent to all key contacts at provider organizations enrolled in the CT Vaccine (Pediatric) Program (CVP), COVID-19 Vaccine Program (CoVP), and CT Vaccine For Adults/317 Program – please read this message in its entirety. *Please feel free to share it with others in your organization who may benefit from the update. Note that all our communications are archived on our web site.*

Dear providers,

Below are some updates to ACIP recommendations based on recent meetings, and some webinar opportunities to learn more. We expect the full, published recommendations to be available in the coming months here. You can sign up to receive updates directly from CDC on the site.

Pediatric Respiratory Syncytial Virus (RSV) Vaccines

The ACIP voted unanimously to recommend and include in the Vaccines for Children Program (VFC) the RSV vaccine nirsevimab (trade name Beyfortus) for all infants who are younger than 8 months and born during – or entering – their first RSV season (typically fall (October) through spring (March)). One dose of nirsevimab can protect infants for 5 months, the length of an average season. A dose of nirsevimab is also recommended for some children between the ages of 8 and 19 months who are at high risk of severe RSV, such as children who are severely immunocompromised, and who are entering their second RSV season. Nirsevimab is a long-acting monoclonal antibody product, which has been shown to reduce the risk of both hospitalizations and healthcare visits for RSV in infants by about 80 percent.

Nirsevimab is expected to be available this fall, possibly early to mid-October. Nirsevimab will be available for all VFC eligible children when it is available on the commercial market. The Department of Public Health (DPH) Immunization Program anticipates that nirsevimab will be available universally for all children regardless of insurance status through the CVP. More information and updates will be shared as we have them.

- **Implementation and plans for monitoring safety and effectiveness[1]**
    - Nirsevimab storage, handling, and administration is similar to other routine vaccines for children. It is administered as an intramuscular injection using

a single-dose pre-filled syringe and can be administered simultaneously with other childhood vaccines.
    - If nirsevimab is administered alone, suspected adverse events (AEs) are reported to MedWatch. If nirsevimab is administered simultaneously with any vaccine, suspected AEs are reported to the Vaccine Adverse Event Reporting System (VAERS); additional reporting to Medwatch not needed. A process is in place to capture misrouted reports. The FDA and CDC will both participate in monitoring safety reports and other safety data sources.
    - CDC will monitor effectiveness of nirsevimab by leveraging existing vaccine effectiveness platforms throughout the season.
- **Clinical considerations[2,3]**
    - For infants born shortly before and during the RSV season, providers should target administration during the birth hospitalization or shortly after discharge, and by one week of age.
    - For infants born before the RSV season, providers should target administration just before the start of the RSV season, such as during a scheduled well child visit.
    - Based on pre-pandemic patterns, nirsevimab could be administered in most of the continental US from October through the end of March.
    - The ACIP added American Indian and Alaska Native Children to those recommended by the AAP who are at increased risk of severe disease in children aged 8-19 months entering their second RSV season based on documented increased incidence of RSV-associated hospitalizations in these groups. Other risk factors include children with chronic lung disease of prematurity who required medical support any time during the 6-month period before the start of the second RSV season, severe immunocompromise, cystic fibrosis who have manifestations of severe lung disease or weight-for-length <10th percentile.

References

1. ACIP Presentation. Peacock G. 3 Aug 2023. Nirsevimab: Implementation Considerations. (Link)
2. ACIP Presentation. Jones J. 3 Aug 2023. Evidence to Recommendations Framework: Nirsevimab Updates. (Link)
3. ACIP Presentation. Jones J. 3 Aug 2023. Proposed Clinical Consideration Updates for Nirsevimab. (Link)

Adult RSV Vaccines

Adults 60 years of age and older may receive a single dose of Respiratory Syncytial Virus (RSV) vaccine, using shared clinical decision-making. Arexvy was approved by the Food and Drug Administration in May, 2023. The CDC will host a call New RSV Vaccines for Adults: General Information and Clinical Guidance, the details of which are at the end of this message.

Pneumococcal Vaccines

- Use of either pneumococcal conjugate vaccines (PCV) PCV15 or PCV20 is recommended for all children aged 2–23 months according to currently recommended PCV dosing and schedules.
- For children with an incomplete PCV vaccination status, use of either PCV15 or PCV20 according to currently recommended PCV dosing and schedules is recommended for:
    - Healthy children aged 24–59 months
    - Children with specified health conditions aged 24 through 71 months. Risk conditions include:
        - cerebrospinal fluid leak; chronic heart disease; chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome, which are included in immunocompromising conditions); chronic liver disease; chronic lung disease (including moderate persistent or severe persistent asthma); cochlear implant; diabetes mellitus; immunocompromising conditions (on maintenance dialysis or with nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; and sickle cell disease and other hemoglobinopathies).
- For children aged 2–18 years with any risk condition who have received all recommended doses of PCV before age 6 years
    - Using ≥1 dose(s) of PCV20: No additional doses of any pneumococcal vaccine are indicated. This recommendation may be updated as additional data become available.
    - Using PCV13 or PCV15 (no PCV20): A dose of PCV20 or PPSV23 using previously recommended dosing and schedules is recommended.
- For children aged 6–18 years with any risk condition who have not received any dose of PCV13, PCV15, or PCV20, a single dose of PCV15 or PCV20 is recommended. When PCV15 is used, it should be followed by a dose of PPSV23 at least 8 weeks later if not previously given.

CDC has indicated that PCV20 (brand name Prevnar 20, a Pfizer product) will become available for ordering during the month of September. We will send out a follow up communication when PCV20 becomes available for ordering from the CVP. CDC will be hosting a webinar about the new recommendations for children and adults; information details are shared below. A PCV20 storage and coding fact sheet is attached to this communication.

Covid-19 Vaccine

In June, the ACIP COVID-19 work group discussed whether a single dose of an updated COVID-19 vaccine may be reasonable for possible future recommendations for 2–4 year olds, instead of a multidose series. The work group felt that 6–23 month olds should receive a multidose series. They also noted that the highest rates of hospitalization currently occur in adults 75+, followed by infants <6 months and adults 65–74 years.

The DPH Immunization Program anticipates that pediatric COVID-19 vaccines will be available universally for all children regardless of insurance status through the CVP.

More information and updates will be shared as we have them. We anticipate an FDA authorization of a new COVID-19 booster formulation in approximately mid-September and ACIP approval shortly thereafter.

Upcoming Immunization Webinars Hosted by CDC

1. **Childhood and Adult Pneumococcal Recommendations** (Current Issues in Immunization Webinar (CIIW) Series)

On **August 23, 2023, at 12:00 p.m. – 1:00 p.m. (ET)**, the Division of Bacterial Diseases (DBD) in the National Center for Immunization and Respiratory Diseases (NCIRD) will host the next Current Issues in Immunization Webinar. Dr. Miwako Kobayashi, MD, MPH, Medical Officer, Division of Bacterial Diseases, NCIRD, CDC will give updates on childhood and adult Pneumococcal recommendations. Participants can join directly at: https://cdcizlearn.adobeconnect.com/ciiw.

2. **New RSV Vaccines for Adults: General Information and Clinical Guidance** (CIIW series)

On **August 30, 2023 at 12:00 p.m. – 1:00 p.m. (ET)**, the Coronavirus and Other Respiratory Viruses Division (CORVD) in the National Center for Immunization and Respiratory Diseases (NCIRD) will host the next Current Issues in Immunization Webinar. Dr. Michael Melgar, MD, Medical Officer, Coronavirus and Other Respiratory Viruses Division, NCIRD, CDC and Dr. Amadea Britton, MD MPH, Medical Officer, Coronavirus and Other Respiratory Viruses Division, NCIRD, CDC will give updates on the new RSV vaccines for adults. Participants can join directly at: https://cdcizlearn.adobeconnect.com/ciiw.

3. On Demand: Clinical Vaccination Guidance for Pregnant People

The Centers for Disease Control and Prevention (CDC) and the American College of Obstetrics and Gynecology (ACOG) continue to emphasize the importance of vaccinations for pregnant people. CDC and ACOG recommend pregnant people get vaccinated against pertussis, influenza, and COVID-19 during each pregnancy to protect themselves and to protect their baby from these infections during the first few months of life. There have been concerning declines in vaccination coverage for Tdap (tetanus, diphtheria, and pertussis) and influenza vaccines, and low uptake of COVID-19 vaccines among pregnant people. In addition, racial and ethnic disparities persist in vaccination coverage among pregnant people.

During this COCA Call, presenters will give a comprehensive overview of timing and promotion of vaccines people should receive during pregnancy to protect themselves, their pregnancies, and their babies, focusing on Tdap, influenza, and COVID-19 vaccines, and provide an update on the respiratory syncytial virus (RSV) vaccine for pregnant people.

4. **We Must Maintain Measles Elimination in the United States: Measles Clinical Presentation, Diagnosis, and Prevention**

Date: Thursday, August 17, 2023, Time: 2:00–3:00 P.M. ET

The United States has maintained the elimination of measles, defined as the absence of continuous disease transmission for ≥12 months, since 2000. However, measles cases can occur when people travel to and from the United States, especially when travelers are unvaccinated or under-vaccinated against measles. Maintaining measles elimination in the United States requires continued investment in the measles vaccination program which was instrumental to achieving elimination. Health care providers and public health authorities need to remain vigilant to rapidly recognize measles and take steps to mitigate spread within communities for continued measles elimination. The Centers for Disease Control and Prevention (CDC) urges all healthcare providers to ensure their patients are up to date on the measles, mumps, and rubella (MMR vaccine). Healthcare providers should consider measles as a diagnosis in anyone with fever (≥101°F or 38.3°C) and a generalized maculopapular rash with cough, coryza, or conjunctivitis who has recently been abroad, especially in countries with ongoing outbreaks.

During this COCA Call, presenters will discuss the history of measles in the United States, review clinical presentation and diagnosis of measles infection, review how to report suspected cases to public health agencies, and outline recommendations for measles vaccination in the United States. Free Continuing Education (CE) will be offered for this call.

Registration is not needed for any of these webinars. Please note that participation is limited. Should an event be full, a recording will be available afterwards.

As always, thank you for your ongoing support and effort to support vaccines.

For the CT DPH Immunization Program, visit: Contact Us

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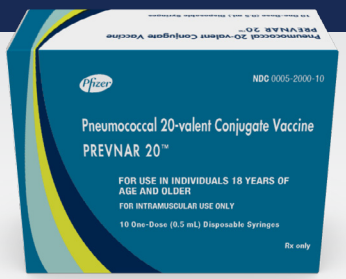
PREVNAR 20® PEDIATRIC INDICATION NOW APPROVED

Prevnar 20® Storage and Coding Fact Sheet



Prevnar 20®
Pneumococcal 20-valent Conjugate Vaccine

How Supplied[1]

0.5 mL suspension for intramuscular injection, supplied in a single-dose pre-filled syringe.

Storage and Handling[1]

- After shipping, Prevnar 20® may arrive at temperatures between 2°C to 25°C (36°F to 77°F)
- Upon receipt, store refrigerated at 2°C to 8°C (36°F to 46°F)
- Syringes should be stored in the refrigerator horizontally to minimize the resuspension time
- Do not freeze. Discard if the vaccine has been frozen
- Prevnar 20® should be administered as soon as possible after being removed from refrigeration
- Prevnar 20® can be administered provided total (cumulative multiple excursions) time out of refrigeration (at temperatures between 8°C and 25°C) does not exceed 96 hours. Cumulative multiple excursions between 0°C and 2°C are also permitted as long as the total time between 0°C and 2°C does not exceed 72 hours. These are not, however, recommendations for storage

Packaging

- Blue box with Prevnar 20® branding. Note that packaging may include the statement "For use in individuals 18 years of age and older"; however, the product can still be administered to pediatric patients because the vaccine formulation and dosage are the same. Based on the transition timing and current inventory, the existing package and the new package may be available at the same time in the United States for up to 6 months

CPT® Code for Prevnar 20®[2]

90677 [Pneumococcal conjugate vaccine, 20 valent (PCV20), for intramuscular use]

CVX Code[3]

216

Billing Code for Diagnosis (ICD-10-CM)[4]

Z23 (Encounter for immunization)

CPT® Code for Pediatric Administration[5]

90460 (Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified healthcare professional; first or only component of each vaccine or toxoid administered)

NDC Number[1]	Description[1]	Wholesale Acquisition Cost[6]
0005-2000-10	Pre-filled Syringe, 1 Dose (10 per package)*	{$2532.14}

CPT® is a registered trademark of the American Medical Association.
CPT=Current Procedural Terminology; CVX=Codes for Vaccine Administered; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification; NDC=National Drug Code.
*Individual syringes are also available (NDC: 0005-2000-02).[1]

Scan or visit prevnar20pediatric.pfizerpro.com to see what expanded serotype coverage could look like for babies.

Please see Indications and Important Safety Information on page 2.
Please click for Prevnar 20® full Prescribing Information.

Pfizer

Billing for Prevnar 20®
Using CMS-1500 or CMS-1450/UB-04 Forms

For populating specific fields of the CMS-1500 (physician office) or CMS-1450/UB-04 (hospital outpatient department) claim forms

Prevnar 20®
Pneumococcal 20-valent Conjugate Vaccine

Information Requested	Enter This Information	CMS-1500 Item Number	CMS-1450/UB-04 Form Locator
Medication information[7]			
CPT® code	90677	24D	FL 44
Full name of medication, dosage, basis of measurement	Prevnar 20®, 0.5 mL	19/24A shaded area	FL 43
Diagnosis code[7]			
ICD-10 code	Z23*	21	FL 67
Administration code[5,7]			
CPT® code	90460	24D	FL 44
11-digit NDC number[6-8†]			
Carton of 10 pre-filled syringes – Individual pre-filled syringe from a carton of 10	0 0005-2000-01	24 (place NDC in the shaded area at the top of the line)	FL 43

Indications

- Prevnar 20® is a vaccine indicated for active immunization for the prevention of 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 individuals 6 weeks of age and older
- Prevnar 20® is a vaccine indicated for active immunization for the prevention of otitis media caused by *S. pneumoniae* serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F in individuals 6 weeks through 5 years of age

Important Safety Information

- Do not administer Prevnar 20® to individuals with a severe allergic reaction (eg, anaphylaxis) to any component of Prevnar 20® or to diphtheria toxoid
- 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®
- 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 risks
- In individuals 2, 4, 6, and 12 through 15 months of age vaccinated with a 4-dose schedule, the most commonly reported solicited adverse reactions (>10%) were irritability, pain at the injection site, drowsiness, decreased appetite, injection site redness, injection site swelling, and fever
- In individuals 15 months through 17 years of age vaccinated with a single dose, the most commonly reported solicited adverse reactions (>10%) were irritability, pain at the injection site, drowsiness, fatigue and muscle pain, decreased appetite, injection site swelling and redness, headache, and fever

*Enter the ICD indicator "0" in item 21 for CMS-1500.
†An additional "0" is placed in front of the NDC number to ensure creation of an 11-digit code that meets general billing standards.

Scan or visit prevnar20pediatric.pfizerpro.com to see what expanded serotype coverage could look like for babies.

Please click for Prevnar 20® full Prescribing Information.

References: 1. Prevnar 20® (Pneumococcal 20-valent Conjugate Vaccine) Prescribing Information, Wyeth Pharmaceuticals LLC, 2023. **2.** Centers for Medicare & Medicaid Services (CMS). Billing and coding: Medicare preventive coverage for certain vaccines. Revised October 1, 2022. Accessed February 27, 2023. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=54767&DocID=A54767. **3.** Centers for Disease Control and Prevention. IIS: Current HL7 standard code set CVX—vaccines administered. Revised February 14, 2022. Accessed February 27, 2023. https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=cvxvis. **4.** 2023 ICD-10-CM Diagnosis Code Z23: Encounter for immunization. https://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z20-Z29/Z23-/Z23. Accessed February 27, 2023. **5.** American Medical Association. CPT categories/new vaccine codes (including incorporation of ACIP abbreviations listing) long descriptors. Updated February 2, 2023. Accessed February 27, 2023. https://www.ama-assn.org/system/files/covid-vaccine-long-descriptors.pdf. **6.** Data on file. Pfizer Inc., New York, NY. **7.** RJ Health Systems. Drug reimbursement coding and pricing advisory. July 2021. **8.** United Healthcare. National Drug Code (NDC) Requirement Policy, Professional and Facility. 2023. Accessed February 27, 2023. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-reimbursement/COMM-National-Drug-Code-Requirement-Policy.pdf.

Manufactured by Wyeth Pharmaceuticals LLC. Marketed by Pfizer Inc.

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