**Pneumococcal Vaccine, Polyvalent**

**[23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23)]**

**Precautions and Contraindications**

Screen all patients for precautions and contraindications to immunization.

**Indications and Usage:**

The **23-Valent Pneumococcal Polysaccharide Vaccine (PPSV23)** is indicated for vaccination against pneumococcal disease caused by those pneumococcal types included in the vaccine.

**Recommended Schedule**

**Note:** All recommended PCV13 [the 13-valent pneumococcal vaccine] doses should be administered prior to PPSV23 [the 23-valent pneumococcal vaccine] vaccination, if possible, among persons for whom both vaccines are recommended. If a dose of PPSV23 is inadvertently given earlier than the recommended interval, the dose need not be repeated. <http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>

Vaccination with PPSV23 vaccine is recommended for selected individuals as follows:

* **Immunocompetent persons:**
* ACIP recommends routine vaccination for persons aged 65 years and older. As described in the package insert, both PCV13 and PPSV23 vaccine are FDA approved for vaccination of persons aged 50 years and older.
* Routine vaccination of all persons aged 65 years and older who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown
	+ - Administer a dose of PCV13 first, followed in series by a dose of PPSV23
		See Box 1 and Table 1 below. The two vaccines should not be co-administered.
		- The dose of PPSV23 should be given at least 1 year after a dose of PCV13. If PPSV23 cannot be given during this time window, the dose of PPSV23 should be given during the next visit. If a dose of PPSV23 is inadvertently given earlier than the recommended interval, the dose need not be repeated.
* Routine use of PCV13 among adults aged 65 years and older who had previous vaccination with PPSV23 at age 65 years and older.
	+ - Adults aged 65 years and older who have previously received one or more doses of PPSV23 also should receive a dose of PCV13 if they have not yet received it.
		- A dose of PCV13 should be given at least 1 year after receipt of the most recent dose of PPSV23.
* Routine use of PCV13 among adults aged 65 years and older who had previous vaccination with PPSV23 before age 65 years who are now aged 65 years and older.
	+ - Adults aged 65 years and older who have previously received one or more doses of PPSV23 also should receive a dose of PCV13 if they have not yet received it. A dose of PCV13 should be given at least 1 year after receipt of the most recent dose of PPSV23.
		- For those for whom an additional dose of PPSV23 is indicated, this subsequent PPSV23 dose should be given at least 1 year after PCV13 and at least 5 years after the most recent dose of PPSV23.
* Persons aged 2 years age and older with chronic pulmonary disease (including chronic obstructive pulmonary disease and emphysema) (Table 1 and Table 2)
* Persons aged 2 years age and older with chronic cardiovascular diseases (including cyanotic congenital heart disease, congestive heart failure, and cardiomyopathies),
* Persons aged 2 years age and older with diabetes mellitus
* Persons aged 2 years and older with alcoholism and chronic liver diseases (including cirrhosis)
* Persons aged 2 years age and older with chronic renal failure or nephrotic syndrome
* Persons aged 2 years and older with functional or anatomic asplenia (including sickle cell disease and splenectomy [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]) and other hemoglobinopathies
* Persons aged 2 years and older with cochlear implants or cerebrospinal fluid leaks
* Persons aged 2 years and older living in special environments or social settings, e.g. residents of nursing homes or other long-term care facilities (including Alaskan Natives and certain American Indian populations)
* Persons aged 19 through 64 years who smoke cigarettes should receive a single dose of PPSV23 and smoking cessation counseling (Table 3)
* Persons aged 19 through 64 years who have asthma should receive a single dose of PPSV23
* **Immunocompromised persons (Vaccination of persons with high-risk conditions with PCV13 and PPSV23, Table 1 through Table 3):**
	+ For children aged 2 through 5 years, including those with HIV infection, malignant neoplasms, leukemia, lymphoma, Hodgkin’s disease, multiple myeloma, generalized malignancy, chronic renal failure or nephrotic syndrome; those receiving immunosuppressive chemotherapy (including corticosteroids) or radiation therapy; and those who have received a solid organ or bone marrow transplant or have congenital immunodeficiency:
		- Administer 1 dose of PCV13 if 3 doses of PCV (PCV7 and/or PCV13) were received previously.
		- Administer 2 doses of PCV13 at least 8 weeks apart if fewer than 3 doses of PCV (PCV7 and/or PCV13)
		- Administer one supplemental dose of PCV13 if four doses of PCV7 or other
		age-appropriate complete PCV7 series was received previously.
		- The minimum interval between doses of PCV (PCV7 or PCV13)
		is 8 weeks.
		- For children with no history of PPSV23 vaccination, administer PPSV23 at least 8 weeks after the most recent dose of PCV13.
	+ Children aged 6 through 18 years, who are PPSV23-naïve children and have not received PCV13 and are at an increased risk for invasive pneumococcal disease (IPD) because of anatomic or functional asplenia (including sickle cell disease [SCD]), HIV infection, cochlear implant, CSF leak, or other immunocompromising condition should receive a single PCV13 dose first, followed 8 or more weeks later by a dose of PPSV23. A second PPSV23 dose is recommended 5 years after the first PPSV23 dose for children with anatomic or functional asplenia (including SCD), HIV infection, or other immunocompromising conditions.
	+ Children aged 6 through 18 years who have not received PCV13; are at increased risk for IPD because of anatomic or functional asplenia (including SCD), HIV infection, CSF leaks, cochlear implants, or other immunocompromising conditions; and who previously received 1 or more doses of PPSV23 should be given a single PCV13 dose 8 or more weeks after the last PPSV23 dose, even if they have received PCV7. If a second PPSV23 dose is indicated, it should be given 5 or more years after the first PPSV23 dose. These children should not receive more than two doses of PPSV23 before age 65 years.
	+ Adults aged 19 years or older with immunocompromising conditions (including chronic renal failure and nephrotic syndrome), functional or anatomic asplenia, cerebrospinal fluid leaks, or cochlear implants who have not previously received PCV13 or PPSV23 should receive a single dose of PCV13 followed by a dose of PPSV23 at least 8 weeks later.
* ACIP recommends routine vaccination for persons aged 65 years and older. As described in the package insert, both PCV13 and PPSV23 vaccine are FDA approved for vaccination of persons aged 50 years and older.
	+ Routine vaccination of all persons aged 65 years and older who have not previously received pneumococcal vaccine or whose previous vaccination history is unknown
		- Administer a dose of PCV13 first, followed in series by a dose of PPSV23.
		See Box 1 and Table 1 below. The two vaccines should not be
		co-administered.
		- The interval between doses of PCV13 and PPSV23 should be 8 weeks or greater for adults aged 65 years and older with immunocompromising conditions, functional or anatomic asplenia, cerebrospinal fluid leaks, or cochlear implants.
	+ Routine use of PCV13 among adults aged 65 years and older who had previous vaccination with PPSV23 at age 65 years and older.
		- Adults aged 65 years and older who have previously received one or more doses of PPSV23 also should receive a dose of PCV13 if they have not yet received it.
		- A dose of PCV13 should be given at least 1 year after receipt of the most recent dose of PPSV23.
	+ Routine use of PCV13 among adults aged 65 years and older who had previous vaccination with PPSV23 before age 65 years who are now aged 65 years and older.
		- Adults aged 65 years and older who have previously received one or more doses of PPSV23 also should receive a dose of PCV13 if they have not yet received it. A dose of PCV13 should be given at least 1 year after receipt of the most recent dose of PPSV23.
		- For those for whom an additional dose of PPSV23 is indicated, this subsequent PPSV23 dose should be given at least 1 year after PCV13 and at least 5 years after the most recent dose of PPSV23

Vaccination with PPSV23 vaccine **IS NOT** recommended for selected individuals as follows:

* **American Indian/Alaska Native children aged 24 through 59 months:**
	+ Routine use of PPSV23 **is not** recommended for Alaska Native or American Indian children aged 24 through 59 months. However, in special situations, public health authorities may recommend the use of PPSV23 after PCV7 for Alaska Native or American Indian children aged 24 through 59 months who are living in areas in which risk of invasive pneumococcal disease is increased
* **American Indian/Alaska Native adults:**
	+ Routine use of PPSV23 **is** **not** recommended for Alaska Native or American Indian persons younger than 65 years old unless they have underlying medical conditions that are PPSV23 indications. However, in special situations, public health authorities may recommend PPSV23 for Alaska Natives and American Indians aged 50 through 64 years who are living in areas in which the risk of invasive pneumococcal disease is increased

**Timing of Vaccination:**

* PPSV23 should be given at least two weeks before elective splenectomy, if possible
* Persons with asymptomatic or symptomatic HIV infection should be vaccinated as soon as possible after their diagnosis is confirmed
* For planning cancer chemotherapy or other immunosuppressive therapy (e.g., for patients with Hodgkin’s disease or those who undergo organ or bone marrow transplantation), pneumococcal vaccine should be administered at least two weeks prior to the initiation of immunosuppressive therapy
* Vaccination during chemotherapy or radiation therapy should be avoided
* Pneumococcal vaccine may be given as early as several months following completion of chemotherapy or radiation therapy for neoplastic disease
* In Hodgkin’s disease immune response to vaccination may be impaired for two years or longer after intensive chemotherapy (with or without radiation)

**Use with Other Vaccines:**

The ACIP states that pneumococcal vaccine may be administered at the same time as influenza vaccine (by separate injection in the other arm) without an increase in side effects or decreased antibody response to either vaccine, <http://www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm>.

ACIP recommends that zoster vaccine and PPSV23 can be given at the same time or any time before or after each other, <http://www.immunize.org/askexperts/experts_zos.asp>. This ACIP recommendation is different from the contents of the ZOSTAVAX package insert that states, “Consider administration of the two vaccines separated by at least 4 weeks,” [http://www.merck.com/product/usa/pi\_circulars/z/zostavax/zostavax\_pi2.pdf](http://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html).

**BOX 1. Recommended intervals for sequential use of PCV13 and PPSV23 for immunocompetent adults aged ≥65 years — Advisory Committee on Immunization Practices, United States**



**Abbreviations:** PCV13 = 13-valent pneumococcal conjugate vaccine;
PPSV23 = 23-valent pneumococcal polysaccharide vaccine.

| **TABLE 1. Summary of recommended intervals, by risk and age groups, for persons with indications to receive PCV13 and PPSV23 sequence — Advisory Committee on Immunization Practices, United States, September 2015**  |
| --- |
| **Risk group/Underlying medical condition** | **Intervals for PCV13–PPSV23 sequence, by age group** | **Intervals for PPSV23–PCV13 sequence, by age group** |
| **24–71 months** | **6–18 years** | **19–64 years** | **≥65 years** | **24–71 months** | **6–18 years** | **19–64 years** | **≥65 years** |
| **No underlying chronic conditions** | **NA** | **NA** | **NA** | **≥1 year** | **NA** | **NA** | **NA** | **≥1 year** |
| **Immunocompetent persons**Chronic heart diseaseChronic lung diseaseDiabetes mellitusAlcoholism\*Chronic liver disease, cirrhosis\*Cigarette smoking\* | ≥8 weeks | NA | NA | ≥1 year | ≥8 weeks | NA | NA | ≥1 year |
| **Immunocompetent persons**Cerebrospinal fluid leakCochlear implant | ≥8 weeks | ≥8 weeks | ≥8 weeks | ≥8 weeks | ≥8 weeks | ≥8 weeks | ≥1 year | ≥1 year |
| **Persons with functional or anatomic asplenia**Sickle cell disease/other hemoglobinopathyCongenital or acquired asplenia | ≥8 weeks | ≥8 weeks | ≥8 weeks | ≥8 weeks | ≥8 weeks | ≥8 weeks | ≥1 year | ≥1 year |
| **Immunocompromised persons**Congenital or acquired immunodeficiencyHuman immunodeficiency virus infectionChronic renal failureNephrotic syndromeLeukemiaLymphomaHodgkin diseaseGeneralized malignancyIatrogenic immunosuppressionSolid organ transplantMultiple myeloma\* | ≥8 weeks | ≥8 weeks | ≥8 weeks | ≥8 weeks | ≥8 weeks | ≥8 weeks | ≥1 year | ≥1 year |
| **Abbreviation:** NA = not applicable, sequential use of PCV13 and PPSV23 is not recommended for these age and risk groups.\* Underlying medical conditions that are not included in the recommendations for children aged <6 years.  |

| **TABLE 2. Underlying medical conditions that are indications for pneumococcal vaccination among children, by risk group --- ACIP, United States** [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5911a1.htm](http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/1013-mening-mcv.pdf)[http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/02-13-1-pneumo.pdf](http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/2015-02-2-HPV.pdf) |
| --- |
| **Risk group** | **Condition** |
| Immunocompetent persons | Chronic heart disease\*Chronic lung disease†Diabetes mellitusCerebrospinal fluid leaksCochlear implant |
| Functional or anatomic asplenia | Sickle cell disease and other hemoglobinopathiesCongenital or acquired asplenia, or splenic dysfunction |
| Immunocompromised persons | HIV infectionChronic renal failure and nephrotic syndromeDiseases associated with immunosuppressive chemotherapy or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin disease; or solid organ transplantationCongenital immunodeficiency§ |
| \* Particularly cyanotic congenital heart disease and cardiac failure.† Including asthma if treated with high-dose oral corticosteroid therapy. § Includes B- (humoral) or T-lymphocyte deficiency; complement deficiencies, particularly C1, C2, C3, and  C4 deficiency; and phagocytic disorders (excluding chronic granulomatous disease).  |

| **Table 3**. **Medical conditions or other indications for administration of 13-valent pneumococcal conjugate vaccine (PCV13), as well as indications for 23-valent pneumococcal polysaccharide vaccine (PPSV23) administration and revaccination for children aged 6-18 years, and adults aged 19 through 64 years.\*** [**http://www.cdc.gov/mmwr/pdf/wk/mm6225.pdf**](https://gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Menhibrix/pdf/MENHIBRIX.PDF) |
| --- |
| **Risk Group**  | **Underlying Medical Condition** | **PCV13** | **PPSV23** |
| **Recommended**  | **Recommended**  | **Revaccination 5 years after first dose** |
| Immunocompetent persons  | Chronic heart disease **†** |  | X |  |
| Chronic lung disease **§** |  | X |  |
| Diabetes mellitus  |  | X |  |
| CSF leaks  | X | X |  |
| Cochlear implants  | X | X |  |
| Alcoholism  |  | X |  |
| Chronic liver disease, cirrhosis  |  | X |  |
| Cigarette smoking  |  | X |  |
| Persons with functional or anatomic asplenia  | Sickle cell disease/other hemoglobinopathies  | X | X | X |
| Congenital or acquired asplenia  | X | X | X |
| Immunocompromised persons  | Congenital or acquired immunodeficiencies ¶ | X | X | X |
| HIV infection  | X | X | X |
| Chronic renal failure  | X | X | X |
| Nephrotic syndrome  | X | X | X |
| Leukemia  | X | X | X |
| Lymphoma  | X | X | X |
| Hodgkin disease  | X | X | X |
| Generalized malignancy  | X | X | X |
| Iatrogenic immunosuppression **\*\***  | X | X | X |
| Solid organ transplant  | X | X | X |
| Multiple myeloma  | X | X | X |
| **\*** Both PCV13 and PPSV23 should be administered routinely in series to all adults aged 65 years and older, regardless of previous history of vaccination with pneumococcal vaccine before age 65 years (See pages 1 and 2).**†** Including congestive heart failure and cardiomyopathies, excluding hypertension.**§** Including chronic obstructive pulmonary disease, emphysema, and asthma.**¶** Includes B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease).**\*\*** Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy. |

**Revaccination:**

* Revaccination of immunocompetent persons previously vaccinated with PPSV23 vaccine is not routinely recommended.
* However, revaccination once is recommended for persons aged 2 years and older who are at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels, provided that at least five years have passed since receipt of a first dose of pneumococcal vaccine.
* The highest risk group includes persons with functional or anatomic asplenia (e.g., sickle cell disease or splenectomy), HIV infection, leukemia, lymphoma, Hodgkin’s disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome, or other conditions associated with immunosuppression (e.g.,  organ or bone marrow transplantation), and those receiving immunosuppressive chemotherapy (including long-term systemic corticosteroids).
* For children, a second dose of PPSV23 is recommended 5 years after the first dose of PPSV23 for persons aged 2 years and older who are immunocompromised, have sickle cell disease or functional or anatomic asplenia
* If prior vaccination status is unknown for patients in the high-risk group, patients should be given pneumococcal vaccine.
* All persons aged 65 years and older who received PPSV23 when aged <65 years and for whom an additional dose of PPSV23 is indicated when aged ≥65 years, this subsequent PPSV23 should be given ≥1 year after PCV13 and ≥5 years after the most recent dose of PPSV23..
* Because data are insufficient concerning the safety of PPSV23 vaccine when administered three or more times, revaccination following a second dose is not routinely recommended.

**Warnings:**

* For planning cancer chemotherapy or other immunosuppressive therapy (e.g., for patients with Hodgkin’s disease or those who undergo organ or bone marrow transplantation), the timing of vaccination is critical, (See Timing of Vaccination)
* If the vaccine is used in persons receiving immunosuppressive therapy, the expected serum antibody response may not be obtained and potential impairment of future immune responses to pneumococcal antigens may occur, (See Timing of Vaccination)
* Intradermal administration may cause severe local reactions.

**Dosage and Route**

Administer a single 0.5 mL dose of PPSV23 vaccine, intramuscularly (IM) or subcutaneously (SQ), according to the recommended schedule***. Do not inject intravenously or intradermally****.*

* **Always check the package insert prior to administration of any vaccine**.

**Anatomical Site**

* IM in the deltoid muscle or lateral mid-thigh; as with other intramuscular injections, use with caution in patients on anticoagulant therapy.
* SQ anterolateral fat of thigh for young children, posterolateral fat of upper arm for children & adults.

**Precautions (See the package insert for a complete listing of precautions):**

* Safety and effectiveness in children below the age of two (2) years have not been established. PPSV23 vaccine is not recommended in this age group.
* It is not known whether PPSV23 vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. PPSV23 vaccine should be given to a pregnant woman only if clearly indicated.
* It is not known whether PPSV23 is excreted in human milk; caution should be exercised when PPSV23 vaccine is administered to a nursing woman.

**Contraindications**

Hypersensitivity to any component of the vaccine.

**Adverse Events**

* See the product’s package insert
* See Adverse Events Following Vaccinations page of this section

**Storage and Handling**

* Store in refrigerator at 36oF – 46oF (2oC – 8oC)

**References:**

MMWR September 4, 2015 / 64(34);944-947: Intervals Between PCV13 and PPSV23 Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6434a4.htm?s\_cid=mm6434a4\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5701a8.htm?s_cid=mm6434a4_w)

MMWR September 19, 2014 / 63(37);822-825: Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥65 Years: Recommendations of the Advisory Committee on Immunization Practices (ACIP), [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm)

MMWR June 28, 2013 / 62(25);521-524: Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Children Aged 6–18 Years with Immunocompromising Conditions: Recommendations of the Advisory Committee on Immunization Practices (ACIP), [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6225a3.htm](http://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf)

MMWR: Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP), <http://www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm>.

Immunization Action Coalition, Ask the Experts. Zoster (shingles), “The Zostavax package insert says that clinicians should consider administering zoster vaccine and pneumococcal polysaccharide vaccine (PPSV) at least 4 weeks apart. What does ACIP say about this? <http://www.immunize.org/askexperts/experts_zos.asp>

PPSV23 Vaccine Package Insert (revised 05/2015)

<https://www.merck.com/product/usa/pi_circulars/p/pneumovax_23/pneumovax_pi.pdf>

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