DEPARTMENT OF HUMAN SERVICES
HEALTH SERVICES, OFFICE OF FAMILY HEALTH
IMMUNIZATION PROGRAM

PNEUMOCOCCAL CONJUGATE VACCINE (PCV7)
7-Valent Vaccine

I. <u>ORDER</u>:

1. Screen for contraindications.
2. Provide a current Vaccine Information Statement (VIS), answering any questions.
3. Obtain a signed Vaccine Administration Record (VAR).
   a. Give (0.5 ml) pneumococcal conjugate 7-valent vaccine **intramuscularly** (IM).
   b. May be given simultaneously with other vaccines including influenza and all routine childhood immunizations. Concurrent administration of pneumococcal conjugate (PCV7) and pneumococcal polysaccharide (PPV23) vaccines is not recommended. The safety and efficacy of concurrent vaccination has not been studied.

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Signature Health Officer or Medical Provider Date

II. LICENSED VACCINE FOR PNEUMOCCOCAL DISEASE

Product Name	Vaccine component(s)	Acceptable Age Range	Thimerosal
Prevnar®[1,2] (Wythe)	Polysaccharide conjugate of 7 serotypes of Streptococcus pneumoniae	6 weeks to 59 months[3]	None

[1] Each dose contains 0.125 mg of aluminum phosphate adjuvant.
[2] Shake vigorously immediately prior to use to obtain a uniform suspension in container. After shaking, the vaccine is a homogeneous, white suspension.
[3] PCV7 is not routinely recommended for persons > 59 months of age.

III. RECOMMENDATIONS FOR USE:

Children for whom PCV7 is recommended

1. All children <24 months of age

2. Children aged 24-59 months with the following conditions:
   - Sickle cell disease and other sickle cell hemoglobinopathies, congenital or acquired asplenia, or splenic dysfunction
   - Infection with HIV
   - Immunocompromising conditions, including
     - Congenital immunodeficiencies: B- (humoral) or T-lymphocyte deficiency; complement deficiencies, particularly c1, c2, c3, and c4 deficiency; and phagocytic disorders, excluding chronic granulomatous disease
     - Renal failure and nephrotic syndrome
     - Diseases associated with immunosuppressive therapy or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin's disease; or solid organ transplantation
   - Chronic illness, including
     - Chronic cardiac disease, particularly cyanotic congenital heart disease and cardiac failure
     - Chronic pulmonary disease, excluding asthma unless on high dose corticosteroid therapy
     - Cerebrospinal fluid leaks
     - Diabetes mellitus
     - Recipients of cochlear implants

Children for whom PCV7 should be considered

All children aged 24-59 months, with priority given to:
- Children aged 24-35 months
- Children of Alaska Native or American Indian descent
- Children of African-American descent
- Children who attend group child care centers*

* Defined as a setting outside the home where a child regularly spends ≥4 hours per week with ≥2 unrelated children under adult supervision.

IV. VACCINE SCHEDULES

A. Primary PCV7 Series and booster (infants starting under 7 months of age) [1]

DOSE	MINIMUM AGE[2]	MINIMUM SPACING[2,3]	RECOMMENDED AGE
1	6 weeks	Not applicable	2 months
2	10 weeks	4 weeks after dose #1	4 months
3	14 weeks	4 weeks after dose #2	6 months
4 (booster)	12 months	8 weeks after dose #3	12 months

[1] See table IV B for recommendations for children when ≥2 yrs of age.

[2] For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not need to be repeated. Doses administered 5 days or earlier than the minimum interval or age should be repeated as age appropriate.

[3] When an invalid dose needs to be repeated, the repeat dose should be spaced after the invalid dose by a time equal to or greater than the minimum interval between doses.

IV. B. Recommended PCV7 schedule for previously unvaccinated infants and children by age at time of first vaccination	
Age at 1st Dose	**Series**
2-6 months	3 doses, 8 weeks apart; 4th dose at 12-15 months of age (4 doses total)[1,2]
7-11 months	2 doses, 8 weeks apart; 3rd dose at 12-15 months of age (3 doses total)[1,2]
12-23 months	2 doses, 8 weeks apart[3]
24-59 months[4] Healthy children	1 dose
Children 24-59 months with: Sickle cell disease HIV infection Chronic illness Immunocompromising condition[5,6]	2 doses, 8 weeks apart

[1] For children vaccinated at age < than 1 year, the minimum interval between doses is 4 weeks. Use the minimum spacing for children who start the series late or are more than one month behind the recommended immunization schedule. Recommended spacing may be resumed when the child has received the immunizations appropriate for age.

[2] There should be a minimum of 8 weeks between the last dose of the primary series and the booster dose.

[3] The minimum spacing between doses after 1 year of age is 8 weeks.

[4] PCV7 is not routinely recommended for person >59 months of age.

[5] Recommendations do not include children who have undergone bone marrow transplantation.

[6] Children with some chronic diseases or immune suppression may also be candidates to receive PPV23.(See schedule IV-D).

Adapted from Table 3.46 on pg. 497 of 2003 RED BOOK

IV. C. Catch-up PCV7 Schedule for infants and children of low and moderate risk[1,2]

CURRENT AGE	PREVIOUS PCV7 DOSES	RECOMMENDED REGIMEN
7 - 11 months[3]	None	Two doses 8 weeks apart, then 3rd dose at ≥12 months of age, and ≥8 weeks after dose two (3 doses total)
7 - 11 months[3]	1 dose **or** 2 doses with the first dose given <7 months of age and the 2nd dose given at <10 months of age	One dose ≥8 weeks from previous dose, then a dose at ≥12 months of age and ≥ 8 weeks after previous dose (3 or 4 doses total)
12 - 23 months	None or 1 dose before 12 months of age	Two doses ≥8 weeks apart. (2 doses or 3 doses total)
12 - 23 months	2 doses before 12 months of age	One dose ≥8 weeks after previous dose of PCV7. (3 doses total)
12 - 23 months	3 doses before 12 months of age	One dose ≥8 weeks from previous dose of PCV7 (4 doses total)
24 - 59 months[4,5]	Any incomplete schedule	One dose ≥8 weeks after previous dose of PCV7.[6]

[1] Children at moderate risk of infection include all children 24-35 months; children three and four years old (36-59 months) attending out-of-home care for more than 4 hours per week; children three and four years old (36-59 months) who are of Native American, Alaskan Native or African-American descent. Note that children of American Indian or Alaskan Native descent may also receive a dose of pneumococcal polysaccharide vaccine (PPV23) because of the broader range of pneumococcal serotypes that may cause invasive infections in these groups. See IV-D for the correct timing of doses.

[2] The use of pneumococcal conjugate vaccine does not replace the use of PPV23 in children ≥ 24 months of age with sickle cell disease, asplenia, HIV infection, chronic illness or who are immunocompromised. See IV-D for schedule of both vaccines in older infants and children.

[3] In children <1 year of age, minimum spacing between PCV7 doses is 4 weeks.

[4] Previously unvaccinated healthy children 24-59 months of age should receive a single dose of PCV7. Pneumococcal conjugate vaccine is not routinely recommended for persons >59 months of age.

[5] PPV23 is an acceptable alternative for children 24 months of age and older, although an enhanced immune response and probable reduction of nasopharyngeal carriage favor the use of PCV7 whenever possible.

[6] Children with certain chronic diseases or immunosuppressing conditions should receive 2 doses at least 8 weeks apart. (see Schedule IV-D).

IV. D. Guidelines for pneumococcal immunization with PCV7 and PPV23 vaccines for high risk children 24-59 months of age:[1,2]	
PREVIOUS DOSES	**RECOMMENDATIONS**
4 doses of PCV7	1 dose of PPV23[3] at 24 months, at least 8 weeks after last dose of PCV7
1-3 doses of PCV7	1 dose of PCV7, followed by 1 dose of PPV23[3], at least 8 weeks after last dose of PCV7
1 dose of PPV23[3]	2 doses of PCV7, 8 weeks apart, beginning at least 8 weeks after last dose of PPV23
Neither vaccine	2 doses of PCV7, 8 weeks apart and 1 dose of PPV23[3] 8 weeks after last dose of PCV7

[1] Children at high risk of invasive pneumococcal infection include children with sickle-cell disease (SCD), congenital or acquired asplenia, splenic dysfunction, HIV infection, immunosuppressive conditions such as malignancies (e.g. leukemia, lymphoma, Hodgkins disease); congenital immune deficiency; some B-humoral or T-lymphocyte deficiencies; complement deficiencies, phagocytic disorders (excluding chronic granulomatous disease); those receiving immunosuppressive chemotherapy (including long-term systemic corticosteroids); chronic cardiac disease, in particular cyanotic congenital heart disease and cardiac failure; chronic pulmonary disease, including asthma treated with high-dose oral corticosteroid therapy; cerebrospinal fluid leaks; Diabetes mellitus; cochlear implants; chronic renal insufficiency, including chronic renal failure or nephrotic syndrome; and those who have received a solid organ or bone marrow transplant.

[2] Concurrent administration of pneumococcal conjugate (PCV7) and pneumococcal polysaccharide (PPV23) vaccines is not recommended. The safety and efficacy of concurrent vaccination has not been studied.

[3] If the patient is ≤ 10 years of age and it has been at least 3 years from first dose of PPV23, then consider revaccination with PPV23. Revaccination is only recommended for children with SCD, anatomic or functional asplenia, and for those who are immunocompromised or HIV-infected.

Adapted from table 3.47on pg. 498 of 2003 RED BOOK

V. CONTRAINDICATIONS	VI. PRECAUTIONS
A. Persons who experienced an anaphylactic reaction to a previous dose of pneumococcal vaccine or a vaccine component. B. This vaccine should not be used in persons with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection unless the potential benefit clearly outweighs the risk of administration.	A. Pregnancy: Use in pregnant or nursing women has not been studied. B. Persons with acute, moderate or severe illnesses with or without fever may choose to delay immunization until symptoms have resolved.

VII. SIDE EFFECTS AND ADVERSE EVENTS

TYPE OF EVENT	FREQUENCY OF OCCURRENCE
Erythema, redness and pain at site	Common
Vomiting	6.3%
Fever (>38°C)	13.4%
Restless sleep	21.2%
Irritability	45.8%
Diarrhea	12.8%
Drowsiness	15.9%
Decreased appetite	18.3%
Rash or hives	1.2%

VIII. OTHER CONSIDERATIONS

A. Pneumococcal conjugate vaccine is not recommended for use in adult populations. It is not to be used as a substitute for the pneumococcal polysaccharide vaccine in any adult populations.

B. The use of antibiotic prophylaxis in kids under five years of age with functional or anatomical asplenia, and sickle cell disease continues to be recommended. Parents should consult with their treating physician as to whether children who have not experienced invasive pneumococcal disease and have received the recommended pneumococcal immunization should discontinue prophylaxis after 5 years of age.

C. When an elective splenectomy is performed for any reason, administer PCV7 or PPV23 at least 2 weeks prior to splenectomy.

D. Immunization should precede the initiation of immunocompromising therapy by at least two weeks.

E. Children who have experienced invasive pneumococcal disease should receive all recommended doses of pneumococcal immunization with either vaccine as appropriate for their age and underlying condition. The full series of scheduled doses should be completed even if the series is interrupted by an episode of invasive pneumococcal disease.

F. Children with diseases associated with immunosuppressive therapy or radiation therapy and solid organ transplantation may have a diminished response to the vaccine.

G. For someone with a history of fainting with injections, a 15 minute post immunization observational period is recommended.

H. Vaccine shortages: When there is a shortage of PCV7 vaccine, ACIP in consultation with AAP and AAFP update recommendations periodically depending on the available supply in the US. **Follow the interim guidelines and instructions for use provided for you by Oregon Health Services Immunization Program until the national supply returns to normal**. You can access these guidelines at www.healthoregon.org/imm or call your health education liaison.

IX. ADVERSE EVENT REPORTING

Adverse events following immunization should be reported by public providers to the Immunization Program, Health Services, using a Vaccine Adverse Events Reporting System form (VAERS), according to state guidelines. Private providers report all adverse events directly to VAERS. VAERS phone number: (800) 822-7967, and the website address is www.vaers.org.

X. REFERENCES

1. Pneumococcal Disease. In: *Epidemiology and Prevention of Vaccine-Preventable Diseases* ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds. 8th ed. Washington, Dc: Public Health Foundation, 2004: 233-45. Available at http://www.cdc.gov/nip/publications/pink/pneumo.pdf.
2. Pneumococcal Infections. In: Pickering LK, ed. *Red Book: 2003 Report of the Committee on Infectious Diseases*. 26th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2003: 490-500.
3. AAP Committee on Infectious Diseases Policy Statement:: Recommendations for the Prevention of Pneumococcal Infections, Including the use of Pneumococcal Conjugate Vaccine (Prevnar), Pneumococcal Polysaccharide Vaccine, and Antibiotic Prophylaxis; MMWR, Vol.46, No. RR-8, 4/4/97.
4. CDC Fact Sheet, Use of Vaccines for the Prevention of Meningitis in Persons with Cochlear Implants, 10/3/02.
5. Preventing Pneumococcal Disease Among Infants and Young Children, MMWR, Vol.49, No.RR-9; 10/6/00.
6. *The Medical Letter*, 3/20/00; 42(1074): 25-7.
7. Vaccine package insert.

For more information or to clarify any part of the above order, consult with your health officer or contact Health Services, Immunization Program at (503) 731-4020.

Visit our website at http://www.healthoregon.org/imm
To request material in an alternate format (e.g., braille), please call (503) 731-4020.