**Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and *Haemophilus* b Conjugate
(Tetanus Toxoid Conjugate) Vaccine**

**DTaP-IPV/Hib Combination Vaccine (PENTACEL®)**

**Precautions and Contraindications**

Screen all patients for precautions and contraindications to immunization.

**Indications and Usage:**

**PENTACEL®** vaccine is indicated for active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to *Haemophilus influenzae* type b. **PENTACEL®** vaccine is approved for use in children 6 weeks through 4 years of age (prior to fifth birthday).

**Recommended Schedule**

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| **Administration of PENTACEL®, DTaP-IPV/Hib** |
| **Dose** | **Minimum Age** | **Minimum Interval to the Next Dose** |
| **One (1)**, or any dose | 6 weeks\* | **4 weeks** (dose 1 to dose 2) |
| **Two (2)** | 10 weeks | **4 weeks** (dose 2 to dose 3) |
| **Three (3)** | 14 weeks | **6 months** (dose 3 to dose 4, determined by DTaP and IPV component);  |
| **Four (4)** | **12 months** | Note that both the minimum interval **AND** age must be met for the fourth dose of DTaP, Hib (for **PENTACEL®** or any other formulation) to be counted as valid**;****DTaP dose 5 IS NOT given as PENTACEL® vaccine**.  |

**\***Use of the minimum age and minimum intervals for vaccine administration in the first 6 months of life are recommended only if the vaccine recipient is at risk for imminent exposure to circulating poliovirus.

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| **Dose** | **Maximum age for PENTACEL® Administration** |
| Any Dose  | 4 years, 364 days (i.e., do not administer at age 5 years or older.) |

**MMWR dated December 19, 2007 CDC recommended that PedvaxHIB, a Hib capsular polysaccharide (i.e. polyribosylribitol phosphate [PRP]), be used for vaccinating American Indian/Alaska Native (AI/AN) children due to the increased risk of developing Hib disease in the first six months of life; therefore, PENTACEL® IS NOT RECOMMENDED FOR USE IN THE AI/AN POPULATION.**

**PENTACEL®** vaccine is approved for administration as 4-dose series routinely given at 2, 4, and 6 months, and 15 through 18 months of age. The first dose may be give as early as 6 weeks of age.

* Four doses of **PENTACEL®** vaccine constitute a primary immunization course against pertussis.
* Three doses of **PENTACEL®** vaccine constitute a primary immunization course against diphtheria, tetanus, *H influenzae* type b invasive disease, and poliomyelitis.
* The fourth dose of **PENTACEL®** constitutes a booster vaccination against diphtheria, tetanus, *H influenzae* type b invasive disease and poliomyelitis.

If a decision is made to withhold pertussis vaccine, vaccination against diphtheria, tetanus, poliomyelitis and invasive disease due to *H influenzae* type be should be provided with brands of vaccines other than **PENTACEL®**.

Children who have completed a four-dose series with **PENTACEL®** should receive a fifth dose of DTaP vaccine at 4 through 6 years of age. Because the pertussis antigens in DAPTACEL**®** brand DTaP vaccine are the same as those in **PENTACEL®**, these children should receive DAPTACEL**®** vaccine as their fifth dose of DTaP.

Data are not available to evaluate the safety of DAPTACEL**®** vaccine following four previous doses of **PENTACEL®** vaccine **[See the product’s package insert]**.

ACIP has clarified the poliovirus vaccination schedule to be used for specific combination vaccines. When DTaP-IPV/Hib (**PENTACEL®**) is used to provide 4 doses at ages 2, 4, 6, and 15 through 18 months, an additional booster dose of age-appropriate IPV-containing vaccine (IPV [IPOL] or DTaP-IPV (KINRIX**®**]) should be administered at age 4 through 6 years. This will result in a 5-dose IPV vaccine series, which is considered acceptable by ACIP.
DTaP-IPV/Hib (**PENTACEL®**) is not indicated for the booster dose at age 4 through 6 years. ACIP recommends that the minimum interval from dose #4 to dose #5 should be at least 6 months to provide an optimum booster response. In accordance with existing recommendations, if a child misses an IPV dose at age 4 through 6 years, the child should receive a booster dose as soon as feasible (MMWR August 7, 2009/ 58(30); 830).

**Children Previously Vaccinated with One or More Doses of DAPTACEL® Vaccine:** **PENTACEL®** vaccine may be used to complete the first 4 doses of the DTaP series in infants and children who have received one or more doses of DAPTACEL**®** and are also scheduled to receive the other antigens of **PENTACEL®** vaccine, however, the safety and efficacy of **PENTACEL®** vaccine in such infants have not been evaluated **[See the product’s package insert**]

**Children Previously Vaccinated with One or More Doses of IPV:** **PENTACEL®** vaccine may be used in the 4 dose IPV series in infants and children who have received 1 or more doses of another licensed IPV vaccine and are also scheduled to receive the other antigens of **PENTACEL®** vaccine, however, the safety and efficacy of **PENTACEL®** in such infants have not been evaluated **[See the product’s package insert]**. **PENTACEL®** is not indicated for the booster dose at age 4 through 6 years.

**Children Previously Vaccinated with One or More Doses of *Haemophilus* b Conjugate Vaccine:** **PENTACEL®** may be used to complete the vaccination series in infants and children previously vaccinated with one or more doses of a *Haemophilus* b conjugate vaccine (either separately administered or as part of another combination vaccine), who are also scheduled to receive the other antigens of **PENTACEL®** vaccine, however, the safety and efficacy of **PENTACEL®** vaccine in such infants have not been evaluated **[See the product’s package insert**]. If different brands of *Haemophilus* b conjugate vaccines are administered to complete the series, three primary immunizing doses are needed, followed by a booster dose.

**Dosage and Route**

Give **PENTACEL®** vaccine 0.5 mL intramuscularly (IM).

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

**Anatomical Site**

The preferred sites are the anterolateral aspects of the thigh or into the deltoid muscle. The vaccine should not be injected into the gluteal area or areas where there is a major nerve trunk.

**Preparation for Administration:**

**PENTACEL®** vaccine should be inspected visually for extraneous particulate matter and/or discoloration before administration. If these conditions exist, **PENTACEL®** vaccine should not be administered.

**Reconstitution of Freeze-Dried Product and Withdrawal from Stoppered Vial:**

* Gently shake the vial of DTaP-IPV component
* Withdraw the entire liquid content
* Insert the syringe needle through the stopper of the vial of lyophilized ActHIB vaccine component and inject the liquid into the vial.
* Shake vial thoroughly
* After reconstitution, immediately withdraw 0.5 mL of **PENTACEL®** vaccine and administer intramuscularly
* **PENTACEL®** should be used immediately after reconstitution

**The contraindications and precautions for DTaP-IPV/Hib are the same as they would be for any of its individual component vaccines. Please refer to the package insert for a complete list of contraindications and precautions and to the other immunization protocols for the individual component vaccines.**

**Precautions**

* Before administration, a patient’s health status and medical history should be reviewed to determine whether any contraindications exist and to assess the benefits and risks.
* For infants or children at higher risk for seizures than the general population an appropriate antipyretic may be administered at the time of vaccination of any acellular pertussis containing vaccine, including **PENTACEL®**, and for the following 24 hours.
* If **PENTACEL®** is administered to immunocompromised persons, including persons receiving immunosuppressive therapy, the expected immune response may not be obtained.

**Contraindications to the Administration of PENTACEL®**

* A severe allergic reaction (e.g. anaphylaxis) after a previous dose of **PENTACEL®** vaccine, any ingredient of this vaccine, or any other tetanus toxoid, diphtheria toxoid, pertussis-containing vaccine, inactivated poliovirus vaccine or *H influenzae* type b vaccine (see **PENTACEL®** package insert)
* **PENTACEL®** vaccine is not recommended for persons before the age of 6 weeks or for those persons 5 years of age and older.
* The following medical events are contraindications to administration of any pertussis-containing vaccine, including **PENTACEL®** vaccine.
	+ Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) within 7 days of administration of a previous dose of a pertussis containing vaccine that is not attributable to another identifiable cause
	+ Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy. Pertussis vaccine should not be administered to individuals with such conditions until the neurologic status is clarified and stabilized.

**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)
* DO NOT FREEZE; discard **PENTACEL®** vaccine that has been frozen
* **PENTACEL®** vaccine should be used immediately after reconstitution

**Additional Information:**

* Vaccine Information Statements (VIS) -- No specific VIS is available for **PENTACEL**®
* CPT Code 90698
* **Concomitant Administration with Other Vaccines:** In clinical trials (See package insert), **PENTACEL®** was administered concomitantly, at separate sites, with pneumococcal conjugate vaccine (PCV7), hepatitis B vaccine, measles, mumps, rubella (MMR) vaccine, and varicella vaccine.
* **Different lot numbers for the different components of DTaP-IPV/Hib are included on the DTaP-IPV vial and on the Hib powder vial. Providers should record lot numbers separately for the DTaP-IPV and Hib components, as stated in the MMWR dated October 3, 2008.**

Last updated October 1, 2009 and August 1, 2012