Standing Orders for Administering DTaP-IPV-HepB (PEDIARIX®) Combination Diphtheria, Tetanus and Pertussis-Polio-Hepatitis B Vaccine

**Purpose:** To reduce the morbidity and mortality from diphtheria, tetanus, pertussis, polio and hepatitis B (DTaP-IPV-HepB) diseases by vaccinating children who meet the criteria established by the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices (ACIP) and FDA product labeling and the Department of Defense (DoD).

**Policy:** Under these standing orders, eligible nurses and other healthcare professionals working within their scope of practice may vaccinate pediatric patients who meet the criteria below.

**Procedure:**
1. Identify all children between 6 weeks through 6 years of age (prior to 7th birthday) in need of vaccination against DTaP-IPV-HepB based on the following criteria:
   - currently healthy child 6 weeks through 7 months of age who needs DTaP doses 1,2 or 3; Hepatitis B doses 1,2,3, or 4 (if birth dose was given); and IPV doses 1,2, or 3. Proceed to vaccinate if remaining criteria are met:
     - If child is younger than age 6 weeks, do not vaccinate (reschedule vaccination when child meets age criteria).
     - If child is 7 months or older or child is more than 1 month behind routine schedule, follow protocol for PEDIARIX catch-up vaccination (see #5 below).

2. Screen all patients for contraindications and precautions to the PEDIARIX (DTaP-IPV-HepB) vaccine:
   **Contraindications:**
   - severe allergic reaction (anaphylaxis) after a previous dose of any diphtheria toxoid, tetanus toxoid, pertussis, hepatitis B, or poliovirus-containing vaccine, or to any component of PEDIARIX (including yeast, neomycin and polymyxin B). For information on vaccine components, refer to the manufacturers’ package insert or go to [http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf](http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf)
   - encephalopathy within 7 days of administration of a previous pertussis-containing vaccine.
   - progressive neurologic disorders (including infantile spasms, uncontrolled epilepsy or progressive encephalopathy)

   **Precautions:**
   - if Guillain-Barré syndrome occurs within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give PEDIARIX should be based on potential benefits and risks.
   - the tip caps of the prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex-sensitive individuals
   - collapse or shock-like state (hypotonic hypo-responsive episode) within 48 hours of receiving a previous dose of PEDIARIX or DTaP
   - child experienced a fever of 105°F or higher within 48 hours after vaccination with a previous dose of PEDIARIX or DTaP. Child experienced a fever of 105°F or higher within 48 hours after vaccination with a previous dose of PEDIARIX or DTaP. Refer to primary care provider for evaluation of risk and benefit of DTaP vaccination versus DT vaccination
   - persistent, inconsolable crying lasting 3 or more hours within 48 hours of receiving a
previous dose of PEDIARIX or DTaP
- seizure within 3 days of receiving a previous dose of PEDIARIX or DTaP
- For questions or concerns, consider consulting the DHA Immunization Healthcare Branch at 877-438-8222, Option 1.

3. Provide all patients (or their parent/legal representative) with a copy of the most current federal
Vaccine Information Statement (VIS). You must document, in the patient’s medical record, the
publication date of the VIS and the date it was given to the patient (parent/legal representative).
Provide non-English speaking patients with a copy of the VIS in their native language, if
available and preferred; these can be found at www.immunize.org/vis.

4. Provide routine vaccination with PEDIARIX (DTaP-IPV-HepB) vaccine at 2, 4 and 6
months of age. Administer 0.5 mL DTaP-IPV-HepB vaccine intramuscularly. The preferred
administration site is the anterolateral aspect of the thigh for children younger than 1 year.
- In older children, the deltoid muscle is usually large enough for an intramuscular injection.
- Choose needle gauge and length appropriate to the child’s age, body mass and site
selected (deltoid vs. vastus lateralis): a 22–25 gauge and 5/8- to 1-inch needle.

5. For children (up to age 6 years) who have not received DTaP-IPV-HepB vaccine at the ages
specified above in #4, give one dose at the earliest opportunity. See table below for
subsequent doses:

<table>
<thead>
<tr>
<th>Dose</th>
<th>Minimum Age Given</th>
<th>Time Between Doses</th>
</tr>
</thead>
<tbody>
<tr>
<td>#2</td>
<td>10 weeks</td>
<td>Minimum of 4 weeks from Dose #1</td>
</tr>
<tr>
<td>#3</td>
<td>6 months</td>
<td>Minimum of 8 weeks from Dose #2; must be 16 weeks from Dose #1</td>
</tr>
</tbody>
</table>

DTaP-IPV-HepB is not approved for the 4th or 5th doses of DTaP or the 4th dose of IPV. A
child who received the birth dose of monovalent Hepatitis B vaccine can receive the full 3-
dose series of PEDIARIX (DTaP-IPV-HepB) as described above.

6. Documentation
- Document all immunizations administered in the electronic health record. Include
date, immunization given, dose, anatomical location of administration, lot number,
manufacturer, Vaccine Information Sheet (VIS) date, and the identification of the
person administering the vaccine. If vaccine was not given, record the reason for
non-receipt.

7. Be prepared to manage a medical emergency related to the administration of vaccines by
having written emergency medical protocol available, as well as equipment and medications.

8. Adverse Events occurring after administration of any vaccine should be reported to the Vaccine
Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by
fax, or by mail. Additional information about VAERS is available by telephone (1-800-822-7967)
or online at https://vaers.hhs.gov.

9. This policy and procedure shall remain in effect for all patients of the _____________________

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until rescinded and/or upon a change in the Medical Director, whichever is earlier.

Medical Director’s Signature

Date