Immunization Program Vaccines for Children Program Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus (DTaP-IPV) Vaccine Summary May 2017

Purpose

Effective May 2, 2017, Quadracel (DTaP-IPV) vaccine, manufactured by Sanofi Pasteur Inc. is available to order through the Iowa VFC Program.

Vaccine Recommendations

Food and Drug Administration (FDA)

• March 24, 2015, the FDA licensed Quadracel for use as the fifth dose in the DTaP series and as a fourth or fifth dose in the IPV series in children aged 4 through 6 years who have received 4 doses of DTap-IPV-Hib (Pentacel, Sanofi Pasteur) and/or DTaP (Daptacel, Sanofi Pasteur) vaccine.

Advisory Committee on Immunization Practices (ACIP)

• <u>Licensure of a Diphtheria and Tetanus Toxoids and Acellular Pertussis</u> <u>Adsorbed and Inactivated Poliovirus Vaccine and Guidance for Use as a</u> <u>Booster Dose; September 4, 2015</u>

VFC Resolution

The VFC Program follows the ACIP recommendations for the use of DTaP-IPV vaccine for VFC eligible children 4 through 6 years of age.

ACIP Recommended Schedule for Quadracel Vaccine

Quadracel (Sanofi Pasteur) is a combination DTaP and IPV vaccine. Quadracel is approved for use in children 4 through 6 years of age as the **5th dose of the DTaP series and the 4th dose of the IPOL series** in children who have received 4 doses of Pentacel (DTaP-IPV-Hib, Sanofi Pasteur) and/or Daptacel (DTaP, Sanofi Pasteur) vaccine. It should not be given to children younger than age 4 years.

Quadracel should not be administered to children less than 4 years of age or 7 years of age and older. If Quadracel vaccine is inadvertently administered before 4 years of age for an earlier dose of the DTaP and/or IPV series and if minimum interval requirements have been met, the dose may be counted as valid for the DTaP and/or IPV series and does not need to be repeated. The final dose in the IPV series must be administered at age 4 years and older regardless of the number of previous doses, and with a minimum interval of 6 months from the previous dose.

ACIP recommends the same brand of DTaP be used for each dose in the series. However, vaccination should not be deferred because the type of DTaP vaccine previously administered is unavailable or unknown.

Recommended Dosage

The recommended dose is 0.5mL administered as an intramuscular injection. Refer to product package inserts.

Vaccine Storage and Handling

- Store refrigerated at 2 8°C, 36 46°F.
- Do not freeze.
- Product which has been exposed to out of range temperatures should not be used.
- Do not use after expiration date shown on the label.

Precautions

- Carefully consider benefits and risks before administering Quadracel to persons with a history of:
 - o Fever ≥ 40.5 degrees C (≥105 degrees F), hypotonic-hypo responsive episode (HHE) or persistent, inconsolable crying lasting ≥3 hours within 48 hours after a previous pertussis-containing vaccine.
 - Seizures within three days after a previous pertussis-containing vaccine.
- If Guillain-Barre syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give any tetanus toxoid-containing vaccine, including Quadracel should be based on careful consideration of the potential benefits and possible risks.

Contraindications

- Severe allergic reaction to any ingredient of Quadracel, or following any diphtheria toxoid, tetanus toxoid, pertussis-containing vaccine or inactivated poliovirus vaccine.
- Encephalopathy within 7 days of a previous pertussis-containing vaccine with no other identifiable cause.
- Progressive neurologic disorder until a treatment regimen has been established and the condition has stabilized.

IDPH/Immunization Program Recommendations

The IDPH, Immunization Program routinely follows and promotes the ACIP Recommended Immunization Schedule. The Immunization Program is implementing Quadracel vaccine in accordance with the ACIP recommendations and the VFC resolution.

CPT Code

Quadracel (Sanofi Pasteur Inc.): 90696