Vaccines for Children (VFC) Program
Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, *Haemophilus influenzae* Type b Conjugate, and Hepatitis B (DTaP-IPV-Hib-HepB) Vaccine Summary
July 13, 2021

Purpose of vaccine summary

- Effective July 13, 2021, Vaxelis (DTaP-IPV-Hib-HepB) vaccine, manufactured by Sanofi Pasteur Limited and distributed by Merck Sharp and Dohme Corp. and Sanofi Pasteur Inc. is available to order through the Iowa VFC Program.

Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, *Haemophilus influenzae* Type b Conjugate, and Hepatitis B Vaccine Recommendations

Food and Drug Administration (FDA)

- December 21, 2018 the FDA licensed Vaxelis for use in children aged 6 weeks through 4 years; it is indicated as a 3-dose series for infants at 2, 4, and 6 months.

Advisory Committee on Immunization Practices (ACIP)

- **Licensure of a Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, Haemophilus influenzae Type b Conjugate, and Hepatitis B Vaccine, and Guidance for Use in Infants**

VFC Resolution

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

ACIP Recommended Schedule for DTaP-IPV-Hib-HepB Vaccines

Vaxelis is a combination DTaP-IPV-Hib-HepB vaccine. Vaxelis is approved for use in children 6 weeks through 4 years of age (prior to the 5th birthday) and is indicated for the 3 dose primary vaccination series in infants at ages 2, 4, and 6 months. The recommended minimum age for the third dose of DTaP-IPV-Hib-HepB is 24 weeks, the minimum age for completion of the Hep B vaccine series. It should not be used in children less than 6 weeks of age or older than 4 years of age. Vaxelis may be used for children younger than age 5 years of age requiring a catch-up primary series, using appropriate minimum intervals. It is not approved as the booster dose of DTaP (dose 4 or 5) or IPV (dose 4) or Hib (dose 4). If Vaxelis is inadvertently administered as a booster dose, it may count as valid and the dose does not need to be repeated if minimum ages and intervals are maintained.

Recommended Dosage and Administration
The recommended dose is 0.5mL administered as an intramuscular injection. Just before use, shake the vial or syringe until a uniform, white, cloudy suspension results. Refer to product package insert.

Vaccine Storage and Handling
- Store refrigerated at 2 - 8°C (36 - 46°F).
- Do not freeze. Protect from light.
- Do not use product exposed to out of range temperatures.
- Do not use after expiration date shown on the label.

Precautions
- Moderate or severe acute illness with or without fever.
- Guillain-Barre' syndrome (GBS) within 6 weeks after a previous dose of tetanus toxoid-containing vaccine.
- History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria or tetanus toxoid-containing vaccine; defer vaccination until at least 10 years have elapsed since last tetanus toxoid-containing vaccine.
- Progressive or unstable neurologic disorder (including infantile spasms for DTaP), uncontrolled seizures or progressive encephalopathy; defer until a treatment regimen has been established and the condition stabilized.

Contraindications
- Severe allergic reaction to any ingredient of Vaxelis, or following any diphtheria toxoid, tetanus toxoid, pertussis-containing vaccine, inactivated poliovirus vaccine, *haemophilus influenzae* type b (Hib) or hepatitis B vaccine.
- Hypersensitivity to yeast.
- Encephalopathy within 7 days of a previous pertussis-containing vaccine with no other identifiable cause.

IDPH/Immunization Program Recommendations
The IDPH Immunization Program routinely follows and promotes the ACIP Recommended Immunization Schedule. The Immunization Program is implementing Vaxelis vaccine in accordance with the ACIP recommendations and the federal VFC resolution.

CPT Code Vaxelis: 90697