Standing Orders for Administering GARDASIL®9 to Children and Teens

Purpose: To reduce morbidity and mortality from human papillomavirus (HPV) infection by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), the Food and Drug Administration (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 and teens ages 9-17 years who have not completed the HPV vaccination series.
   Note: HPV vaccine is indicated for individuals aged 9-26 years of age. Please see HPV adult standing orders if vaccinating an individual 18 years or older.
   The series consists of 2 or 3 doses depending on age at time of vaccination. See below for details.

2. Screen all patients for contraindications and precautions to HPV vaccine:
   Contraindications:
   - a history of a serious allergic reaction (e.g., anaphylaxis) after a previous dose of HPV vaccine or to a HPV vaccine component e.g., yeast for 4-valent (4vHPV) or 9-valent (9vHPV) Gardasil vaccines made by Merck. 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

   Precautions:
   - moderate or severe acute illness with or without fever
   - pregnancy; delay vaccination until after completion of the pregnancy
   - because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is strongly recommended.
   - consider consulting the DHA-Immunization Healthcare for questions or concerns about contraindications or precautions

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 Gardasil 9 (9vHPV) to males and females in accordance with the ages noted below:
   - Routine vaccination is recommended for boys and girls at age 11-12 years of age. Note, this vaccine may be administered to girls or boys as young as age 9 years. For boys and girls aged 9-14 years (except immunocompromised), administer a 2-dose series of 9vHPV at 0 and 6-12 months.
   - Provide 9vHPV vaccine in a 3-dose schedule at 0, 2, and 6 calendar months for all males and females aged 15-17 years old and all immunocompromised patients (9-26 years) who have not been previously vaccinated.
   - Administer 0.5 mL 9vHPV vaccine intramuscularly (22–25 gauge, 1–1½” needle) in the deltoid muscle; the anterolateral thigh muscle may be used if deltoid is inadequate. (Note: a ¾” needle may be used for children and teens weighing less than 130 lbs for injection in the deltoid muscle only if the subcutaneous tissue is not bunched and the injection is made at a 90˚ angle.)

5. For children and teens (through age 17 years) who have not received HPV vaccine at the ages and/or
intervals specified in #4, administer:
- one dose of Gardasil 9 at the earliest opportunity and then schedule subsequent doses to complete the age-appropriate schedule
- for the 2-dose schedule observe a minimum interval of 5 months between the first and second dose. If the second dose is administered earlier than 5 months after the first dose, administer a third dose at least 4 months after the second dose
- for the 3-dose schedule observe a minimum interval of 4 weeks between the first and second doses, 12 weeks between the second and third doses, and at least 24 weeks between the first and third doses

The number of recommended doses is based on the age at administration of the first dose. Of note, these minimum intervals are per ACIP recommendations and represent the current standard of care, but are not FDA-approved by the product insert and thus not covered under these standing orders. Please obtain an order from the patient’s primary care provider for the administration of the vaccines via this catch-up schedule.

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

Medical Director’s Signature ___________________________ Date __________

Reviewed by DHA-IHB, March 2019