American Academy of Pediatrics

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HPV Vaccine Implementation Guidance
Updated May 2015

The American Academy of Pediatrics (AAP) has developed the following implementation guidance in response to the recent updated recommendations from the AAP and the Centers for Disease Control and Prevention (CDC) for the routine use of 9-valent human papillomavirus vaccine (HPV9 [types 6, 11, 16, 18, 31, 33, 45, 52, and 58], Gardasil 9 [Merck & Co Inc., Whitehouse Station, NJ]). HPV9 is licensed by the FDA for use in females ages 9 through 26 and in males ages 9 through 15. **The American Academy of Pediatrics and the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention recommend HPV9, HPV4 (as availabilities last), or HPV2 vaccine for routine immunization of females 11 or 12 years of age, and recommend either HPV9 or HPV4 (as availabilities last) for routine immunization of males 11 or 12 years of age. The vaccination series can be started as young as 9 years of age, and in the case of sexual abuse, HPV vaccination is recommended beginning at 9 years of age.**

Providers are encouraged to recommend use of this vaccine as they do all other childhood and adolescent vaccines. Current HPV vaccination rates are lower than expected when compared with other adolescent vaccines within the first few years of incorporation into the immunization schedule. Research has demonstrated that parents often are influenced by the strong recommendations of their child's pediatrician, *and opportunities to prevent HPV-related cancer deaths are being missed by physicians focusing on the HPV vaccine as an STI vaccine rather than a cancer prevention vaccine.*

The HPV9, HPV4 (as availabilities last), and HPV2 vaccines also are recommended for females 13 through 26 years of age not previously immunized. HPV9 and HPV4 (as availabilities last) also are recommended for males 13 through 21 years of age not previously immunized. Males 22 through 26 years of age may be immunized with HPV9 or HPV4, and both are recommended for men who have sex with men. Either (HPV 4 or 9) is also recommended for people who are immunocompromised (including those with HIV infection) through 26 years of age. HPV vaccines are not licensed for use in people older than 26 years of age.

Please access the full set of recommendations (eg clinical manifestations, etiology, epidemiology, diagnostic testing, treatment, infection control, and vaccination recommendations) for Human Papillomaviruses in the Red Book 2015.

The CDC recommendations were published in the March 27, 2015 issue of Morbidity and Mortality Weekly Report, and in the *Red Book* 2015 published in May.

Academy Policy: American Academy of Pediatrics. Human Papillomaviruses. In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. **Red Book: 2015 Report of the Committee on Infectious Diseases.** 30th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2015: 576-583.

CDC Policy: •Petrosky E, Bocchini JA, Hariri S, Chesson H, Curtis CR, Saraiya M, et al. Use of 9-Valent Human Papillomavirus (HPV) Vaccine: Updated HPV Vaccination Recommendations of the Advisory Committee on Immunization Practices MMWR. 2015; 64(11); 300-304.

This document is designed to assist practices in implementing these vaccines and it will be updated as new policy and implementation information becomes available. Please see the following sections for more information:

- **Supply**
- **Liability and Risk Communication**
- **Risk Management**
- **Payment**

- **Coding**
- **Patient Education**
- **Additional Resources**

Supply and Ordering

Supply of 9-valent HPV vaccine is anticipated to be adequate to cover a 3-dose series for all 11 to 12 year olds. The CDC and AAP have not expressed a preference for HPV2 (HPV2 [Cervarix; GlaxoSmithKline]), HPV4, or HPV9. All three are currently available, and Merck will not offer programs to exchange stock of HPV4 for HPV9. The return policy for HPV4 remains the same (vaccine can be returned for a refund up to one year after the expiration date). Of note, Merck has stated that HPV4 will be phased out of the market 12-15 months post licensure of HPV9.

Quadrivalent HPV vaccine and HPV9 vaccine are the only vaccines approved for males. Either HPV9, HPV4 or HPV2 vaccine may be used in females.

Liability and Risk Communication

HPV2, HPV4, and HPV9 vaccines are covered by the Vaccine Injury Compensation Program (VICP). Pediatricians should follow the good risk communication and documentation steps for these vaccines as is required for all vaccines covered by the VICP.

An easy way to remember these steps is to follow the 5 **D's**.

- **D**istribute the Vaccine Information Statement (VIS) with each dose of the vaccine. VISs are available for HPV2, HPV4, and HPV9 vaccines. They can be downloaded at:
  http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hpv-cervarix.html
  http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hpv-gardasil.html
  http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hpv-gardasil-9.html
- **D**ouble check to make sure the VIS matches the vaccine being given. If you are administering HPV2, distribute the "Cervarix" VIS. If you are administering HPV4 and HPV9 vaccines, distribute the "Gardasil" VIS.
- **D**iscuss the risks and benefits of the vaccine. This is the central part the informed consent process.
- **D**ocument in each patient's permanent medical record: (1) that the VIS was provided at the time of vaccination; (2) the edition date of each VIS; (3) the name, address, and title of the individual administering a vaccine; (4) the date of vaccine administration; and (5) the vaccine manufacturer and lot number of the vaccine used. This may require updates to the vaccine administration record, electronic medical records, and state immunization registries.
- **D**ialogue with vaccine doubters. When parents refuse immunization, it is important to try to understand their reasoning and maintain a supportive relationship. Risk managers recommend having parents sign an *informed refusal* document. Here is the link to the AAP refusal form:
  http://www.aap.org/immunization/pediatricians/pdf/RefusaltoVaccinate.pdf
  The VICP Web site has an excellent frequently asked question feature. For more information, visit: http://www.hrsa.gov/vaccinecompensation/.

HPV4 and HPV9 should not be given to pregnant women or people with a history of immediate hypersensitivity to yeast.

Because syncope can occur in adolescents after injections and has been reported after HPV immunization, vaccine recipients should sit or lie down for 15 minutes after administration.

Payment

1. Each practice should verify with third-party payers whether the Gardasil, Gardasil9, and Cervarix vaccines are included as covered benefits and how each will be paid. Third-party payers include commercial insurers, Medicaid fee-for–service, Medicaid managed care, and Tricare. Generally, for those payers for whom vaccines are a covered benefit, most third-party payers will base coverage for vaccines on published recommendations by either:

- The Advisory Committee on Immunization Practices (ACIP), approved by the CDC as published in the *MMWR*
- AAP as published in *Pediatrics* or the AAP *Red Book*

Until recommendations are published, health plan claims systems do not recognize the vaccine as a covered benefit.

2. Each contract with third-party payers should be reviewed for provisions for mid-contract inclusions. Make sure the contract includes a clause allowing for mid-contract inclusion of new recommendations with regard to immunizations. Otherwise, you will need to verify with the carriers how they will incorporate new immunization recommendations into the benefits coverage.

3. Contracts should be reviewed regarding payment levels for vaccines. Make sure there is a provision in the fee schedule that allows for payment to be in an amount equal to the **sum** of both the cost of the vaccine and related practice expenses. If health plan payment is set at a level of average wholesale price (AWP) or average sales price (ASP), pediatricians need to identify the source of the AWP or ASP, because there are several proprietary vendors providing these figures. The AAP supports use of the CDC Vaccine Private Sector price list as the basis for the vaccine cost, because this resource is publicly available and is regularly updated as soon as a change in pricing is announced by the manufacturer. This lists the current manufacturer's vaccine price and can be accessed at: http://www.cdc.gov/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html

4. Include a provision in the contract for the health plan to pay not less than the vaccine cost plus related practice expense costs. See the AAP Business Case for Pricing Vaccines for additional information at https://www.aap.org/en-us/professional-resources/practice-support/financing-and-payment/Documents/Private/BusCasePricingVacc.pdf. In addition, sample contract language on vaccines is available in the *Vaccine Addendum to Payer Contracts at https://www.aap.org/en-us/my-aap/Documents/VaccineAddendumtoPayerContracts.pdf*

5. In addition to the payment for the vaccine and related expenses, make sure there is payment for the immunization administration, which is a separate expense. For information on the total direct and indirect costs of immunizations, see the AAP *Business Case for Pricing Vaccines and Immunization Administration* on the AAP *My AAP* website at: https://www.aap.org/en-us/professional-resources/practice-support/financing-and-payment/Documents/Private/BusCasePricingImm.pdf

6. Check with your state regarding inclusion of the vaccine in the Vaccines for Children (VFC) program. The VFC program provides the vaccine product at no cost to the practice. Physician practices may charge an administration fee. VFC is not an option for children who have private health insurance benefits available for immunizations. This program is for children from birth through 18 years of age who:

   - Are eligible for Medicaid;
   - Have no health insurance;
   - Are American Indian or Alaska Native; or
   - Have health insurance, but it does not cover immunizations AND they go to a federally qualified health center

7. AAP chapters may wish to follow up with Medicaid and SCHIP programs to ensure coverage of both the vaccine and its administration. Children eligible for Medicaid should receive the vaccine through the VFC program.

8. Practices need to develop payment arrangements with families if coverage is not available through a third-party payer. Practices should consider having families sign waivers or advance beneficiary notices (ABNs) clarifying financial responsibility for uncovered services under the health plan. The AAP resource, *Waivers: The Basics for a Pediatric Office can be accessed at: https://www.aap.org/en-us/my-aap/Documents/Waivers2006.pdf*

9. Additional information on immunization financing can be found at https://www.aap.org/en-us/professional-resources/practice-support/Vaccine-Financing-Delivery/Pages/Vaccine-Financing-Delivery.aspx

Coding

Gardasil

The Current Procedural Terminology (CPT) code for the Gardasil vaccine serum is as follows:

90649	Human Papilloma virus vaccine, types 6, 11, 16, 18 quadrivalent (HPV4), 3 dose schedule, for intramuscular use
90651	Human Papillomavirus vaccine types 6, 11, 16, 18, 31, 33, 45, 52, 58, nonavalent (HPV9), 3 dose schedule, for intramuscular use

The International Classification of Diseases – 9th Revision – Clinical Modification (ICD-9-CM) code that would be reported with either vaccine is V04.89 (*Need for prophylactic vaccination against other viral diseases*). Neither CPT nor ICD-9-CM reporting will change based on the sex of the patient. When the International Classification of Diseases- 10th Revision – Clinical Modification (ICD-10-CM) takes effect (currently set for October 1, 2015) the ICD-10-CM code for all vaccine encounters is Z23.

Cervarix

The CPT code for the Cervarix vaccine serum is 90650 (human papillomavirus *(HPV) vaccine, types 16, 18, bivalent, 3 dose schedule, for intramuscular use*). An appropriate vaccine administration code should also be reported in addition to the serum code. The ICD-9-CM code that would be reported with this vaccine is V04.89 (*Need for prophylactic vaccination against other viral diseases*). When the ICD-10-CM takes effect (currently set for October 1, 2015) the ICD-10-CM code for all vaccine encounters is Z23.

Vaccine Administration

When administering an HPV vaccine to a patient 18 years of age and younger which also includes vaccine counseling by a physician or other qualified health care professional (a credentialed nonphysician provider not including clinical staff) on the same day, report CPT code 90460.

If a patient receives an HPV vaccine and the patient is 19 years or older ***or*** there is no vaccine counseling or counseling is performed by clinical staff (eg, registered nurse) only, report code 90471 (or 90472 as appropriate). Note that counseling can be done at the 2nd and 3rd encounters. Therefore if the counseling is done by a physician or other qualified health care professional, CPT code 90460 can be reported for each vaccine as appropriate.

Patient Education: Providing a Strong Recommendation

A physicians' recommendation for the HPV vaccine is the strongest predictor of HPV vaccine acceptance. When providers make a strong recommendation for the vaccine, most parents and adolescents accept the vaccine. An example of a strong, bundled recommendation is "*Today your child should have 3 vaccines. They're designed to protect her/him from the cancers caused by HPV and from meningitis, tetanus, diphtheria, & pertussis.*" or " *Your child needs 3 vaccines today- HPV, Tdap, and meningococcal."*

Patient Education: Supporting a Strong Recommendation

Articles for parents about HPV are available on the AAP parenting Web site HealthyChildren.org. In addition, a revised patient handout will be posted to *Pediatric Patient Education* http://patiented.solutions.aap.org the online subscription resource of the AAP for health care professionals.

Parent Resources from AAP:

- HealthyChildren.org: http://www.healthychildren.org/english/Pages/default.aspx (the official AAP parenting Web site)
- AAP immunization Web site: http://www2.aap.org/immunization/
- Pediatric Patient Education: http://patiented.solutions.aap.org

Parent Resources from CDC:

What Parents Should Know About HPV Vaccine Safety and Effectiveness
- English: http://www.cdc.gov/vaccines/who/teens/vaccines/vaccine-safety.pdf
- Spanish: http://www.cdc.gov/vaccines/who/teens/vaccines/vaccine-safety-sp.pdf

More Information About HPV and HPV Vaccine
- English: http://www.cdc.gov/vaccines/vpd-vac/hpv/downloads/dis-HPV-color-office.pdf
- Spanish: http://www.cdc.gov/vaccines/vpd-vac/hpv/downloads/dis-HPV-color-office-sp.pdf

Additional Resources

AAP Pedialink Course (FREE!): Giving a Strong Provider Recommendation for HPV

Fact Sheets:
- Strategies for raising adolescent immunization rates in offices: http://www2.aap.org/immunization/pediatricians/pdf/TopStrategiesforIncreasingCoverage.pdf
- Addressing common concerns: http://www2.aap.org/immunization/families/faq/AdolescentIZCommonConcerns.pdf

Resources for Working with Media:
- Speaking Tips: http://www.aap.org/en-us/my-aap/advocacy/workingwiththemedia/speaking-tips/Pages/HPV-Vaccine.aspx#sthash.vYFTup3L.dpuf
- HPV Vaccine Speaking Points: http://www.aap.org/en-us/my-aap/advocacy/workingwiththemedia/Pages/Working-with-the-Media.aspx

Resources from CDC:
- HPV Resource Page for Providers: http://www.cdc.gov/vaccines/who/teens/for-hcp/hpv-resources.html
- Tips for Talking to Parents about HPV Vaccine: http://www.cdc.gov/vaccines/who/teens/for-hcp-tipsheet-hpv.pdf
- HPV Q & A: http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm
- HPV Vaccination Safety: http://www.cdc.gov/vaccinesafety/Vaccines/HPV/hpv_faqs.html