



HPV Vaccine Implementation Guidance Updated February 2017

The American Academy of Pediatrics (the Academy) has updated this guidance document in response to the following:

1. The Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) in October, 2016 recommended a 2-dose HPV vaccine series for non-immunocompromised children who begin the series before 15 years of age.
2. The American Academy of Pediatrics (AAP) in February, 2017 recommended a 2-dose HPV vaccine series for non-immunocompromised children who begin the series before 15 years of age.
3. Bivalent HPV vaccine (2vHPV*, Cervarix™) and quadrivalent HPV vaccine (4vHPV**, Gardasil®) are currently not available in the United States.

The AAP and the ACIP of the CDC recommend HPV vaccination with any available vaccine for routine immunization of females at 11 or 12 years of age, and recommend either 9vHPV or 4vHPV** 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 a child who has been the victim of sexual abuse, HPV vaccination is recommended beginning at 9 years of age. As of February 2017, only 9vHPV is available in the US. 2vHPV and 4vHPV are, however, still licensed for use, so reference to these vaccines remains in the event that they become available again.

In October 2016, after considering new clinical trial results, the Food and Drug Administration approved 9vHPV for use in a 2-dose series for girls and boys aged 9 through 14 years. In October 2016, ACIP recommended a 2-dose schedule, with the second dose administered 6–12 months after the first dose, for non-immunocompromised adolescents initiating HPV vaccination in this age range. The AAP published similar recommendations on February 6, 2017.

HPV vaccination with any available vaccine is also recommended for females 13 through 26 years of age not previously immunized or who have not completed the recommended series. 9vHPV and 4vHPV** are recommended for males 13 through 21 years of age not previously immunized or have not completed the recommended series. Males 22 through 26 years of age may be immunized with 9vHPV or 4vHPV**, and both vaccines are recommended for 22 through 26-year-old men who have sex with men and for 22 through 26-year-old males who are immunocompromised (including those with HIV infection). HPV vaccines are not licensed for use in people older than 26 years of age.

Providers should recommend HPV vaccine as they do all other childhood and adolescent vaccines. Research has demonstrated that parents often are influenced by the strong recommendations of their child's pediatrician. Over half of adolescents have received at least 1 dose of HPV vaccine, and HPV vaccination rates continue to rise. *AAP recommends that physicians frame their HPV discussions with families as an opportunity to prevent HPV-related cancer deaths rather than as an STI vaccine.*

*2vHPV is no longer being distributed in the United States. All remaining doses in the United States expired in November 2016.

**4vHPV is no longer being distributed in the United States. All remaining doses will expire by May 2017.

At this time there are no recommendations to revaccinate females or males with 9vHPV vaccine who previously completed a recommended series with 2vHPV or 4vHPV.

Please review the following policy from the American Academy of Pediatrics and Centers for Disease Control and Prevention to see the full set of recommendations.

NEW: The CDC recommendations for the 2-dose schedule were published in the December 16, 2016 issue of [Morbidity and Mortality Weekly Report](#) and in the Academy's clinical reports: [The need to optimize adolescent immunization](#) and [Practical Approaches to Optimize Adolescent Immunization](#).

These statements update the policy statement on HPV vaccine published in the March 27, 2015 issue of [Morbidity and Mortality Weekly Report](#), and in the [Red Book 2015](#) published in May, 2015.

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.

Meites E, Kempe A, Markowitz LE. [Use of a 2-Dose Schedule for Human Papillomavirus Vaccination — Updated Recommendations of the Advisory Committee on Immunization Practices](#) (<https://www.cdc.gov/mmwr/volumes/65/wr/mm6549a5.htm>) MMWR. 2016;65(49);1405-8.

NEW: The Academy's 2 dose recommendations can be found within the following adolescent immunization clinical reports.

Bernstein H, Bocchini J; American Academy of Pediatrics, Committee on Infectious Diseases. The need to optimize adolescent immunization. *Pediatrics*. 2017;139(3):e20174186. Available at: <http://pediatrics.aappublications.org/content/early/2017/02/02/peds.2016-4186>

Bernstein H, Bocchini J; American Academy of Pediatrics, Committee on Infectious Diseases. Practical Approaches to Optimize Adolescent Immunization. *Pediatrics*. 2017;139(3):e20174187. Available at: <http://pediatrics.aappublications.org/content/early/2017/02/02/peds.2016-4187>

Red Book: 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.

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:

- **Dosing Schedule**
- **Supply and Ordering**
- **Liability and Risk Communication**
- **Risk Management**
- **Payment**
- **Coding**
- **Patient Education**
- **Additional Resources**

Dosing Schedule

In October, 2016 the CDC ACIP voted to recommend a 2-dose vaccination series for adolescents receiving their first dose before age 15. Recommended dosing is as follows:

- 2 doses for adolescents receiving a first dose at 9 to 14 years of age:
 - Dose 1 at 0 months
 - Dose 2 at 6-12 months
- 3 doses for persons starting the series at 15 through 26 years of age and 9 through 26 years of age for those who are immunocompromised:
 - Dose 1 at 0 months
 - Dose 2 at 1-2 months
 - Dose 3 at 6 months

Supply and Ordering

Supply of 9vHPV vaccine is anticipated to be adequate to cover a 2-dose or 3-dose series for all 11 to 12 year olds. The CDC and AAP have not expressed a preference for 9vHPV, but 2vHPV [Cervarix™; GlaxoSmithKline] and 4vHPV [Gardasil®; Merck], are no longer distributed in the United States. Merck

will not offer programs to exchange remaining stock of 4vHPV for 9vHPV. The return policy for 4vHPV remains the same (vaccine can be returned for a refund up to one year after the expiration date).

4vHPV vaccine and 9vHPV vaccine are the only vaccines approved for males. Either 9vHPV, 4vHPV or 2vHPV vaccine may be used in females.

Liability and Risk Communication

2vHPV, 4vHPV, and 9vHPV 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. There is a [VIS available](#) for 9vHPV.
- **D**ouble check to make sure the VIS matches the vaccine being given.
- **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](#). The [VICP Web site](#) has an excellent frequently asked question feature.

9vHPV 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, it may be advisable for vaccine recipients to sit or lie down for 15 minutes after administration.

Payment

1. Each practice should verify with third-party payers whether HPV 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.

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. In addition, sample contract language on vaccines is available in the [Vaccine Addendum to Payer Contracts](#) (login required).
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](#) (login required).
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 receive care at 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. Try using the AAP resource, [Waivers: The Basics for a Pediatric Office](#) (login required).
9. Additional information on [Immunization Administration in a State Supplied Vaccine Environment](#) is available.

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 (4vHPV), 3 dose schedule, for intramuscular use
90651	Human Papillomavirus vaccine types 6, 11, 16, 18, 31, 33, 45, 52, 58, nonavalent (9vHPV), 3 dose schedule, for intramuscular use*

*CPT has released an update to the code descriptor for **90651** on January 1, to be implemented on July 1, 2017. The new descriptor includes "2 dose." Use **90651** for the Gardasil 9 now even if only giving 2-doses.

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. Note at the time of publication all Cervarix vaccines have expired. This is being included for informational purposes at this time.

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 all 3 visits. 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.

International Classification of Diseases-10th Revision-Clinical Modification (ICD-10-CM)

The ICD-10-CM code for all vaccine encounters is **Z23**, including the HPV.

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

Parent Resources from AAP:

- HealthyChildren.org (the official AAP parenting Web site)
- [Pediatric Patient Education](http://PediatricPatientEducation.com) (online subscription resource of the AAP for health care professionals)

Parent Resources from CDC:

- [HPV Vaccines: Vaccinating Your Preteen or Teen](http://www.cdc.gov/od/oc/media/pressrel/r081101.htm)
- [HPV Vaccine is Safe – Gardasil](http://www.cdc.gov/od/oc/media/pressrel/r081101.htm)

Additional AAP Resources

- [AAP Immunization Web site](http://www.aap.org/immunization)
- AAP Pedialink Course (FREE!): [Giving a Strong Provider Recommendation for HPV](http://www.aap.org/immunization)
- Fact Sheets:
 - [Strategies for raising immunization rates in offices](http://www.aap.org/immunization)
 - [Addressing common concerns](http://www.aap.org/immunization)

Resources for Working with Media

- [Speaking Tips](http://www.aap.org/immunization) (login required)

Resources from CDC

- [HPV Resource Page for Clinicians](http://www.cdc.gov/od/oc/media/pressrel/r081101.htm)
- [Tips for Talking to Parents about HPV Vaccine](http://www.cdc.gov/od/oc/media/pressrel/r081101.htm)
- [HPV Q & A](http://www.cdc.gov/od/oc/media/pressrel/r081101.htm)
- [HPV Vaccination Safety](http://www.cdc.gov/od/oc/media/pressrel/r081101.htm)