

FDA licensure of 9-valent human papillomavirus vaccine to include males aged 16–26 years — December 14, 2015

On December 10, 2014, 9-valent HPV vaccine (9vHPV) (Gardasil 9, Merck and Co., Inc., Whitehouse Station, NJ) was licensed by the Food and Drug Administration (FDA) for use in females aged 9–26 years and males aged 9–15 years. On December 14, 2015, FDA extended the age indication by including males aged 16–26 years.¹ The inclusion of 16–26 year old males makes the age indication for 9vHPV consistent with that of quadrivalent HPV vaccine (4vHPV) (Gardasil, Merck and Co., Inc., Whitehouse Station, NJ), which is the other HPV vaccine licensed for use in males.

On February 26, 2015, after reviewing 9vHPV clinical trial data (including data for males aged 16–26 years not included in the initial application to FDA), as well as data on vaccine safety, cost-effectiveness modeling, and burden of type-specific HPV-associated disease in the United States, the Advisory Committee on Immunization Practices (ACIP) recommended 9vHPV as one of three HPV vaccines that can be used for routine vaccination.² HPV vaccine is recommended for routine vaccination at age 11 or 12 years (vaccination can be started beginning at age 9 years). ACIP also recommends vaccination for females aged 13–26 years and males aged 13–21 years if not vaccinated previously. Vaccination is also recommended through age 26 years for men who have sex with men and for immunocompromised persons (including those with HIV infection) if not vaccinated previously.³ With FDA approval of 9vHPV for use in males aged 16–26 years, there are no changes to ACIP recommendations, although use in males aged 16–26 years is no longer considered “off-label.”

¹ Food and Drug Administration. Highlights of prescribing information. Gardasil 9 (Human Papillomavirus 9-valent Vaccine, Recombinant). Silver Spring, MD: US Department of Health and Human Services, Food and Drug Administration; 2015. Available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426457.pdf>. Accessed December 15, 2015.

² Petrosky E, Bocchini JA, Hariri S, Chesson H, Curtis CR, Saraiya M, Unger ER, Markowitz LE. [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.

³ Markowitz LE, Dunne EF, Saraiya M, Chesson HW, Curtis CR, Gee J, Bocchini JA, Unger ER. [Human Papillomavirus Vaccination: Recommendations of the Advisory Committee on Immunization Practices \(ACIP\)](#). *MMWR*. 2014; 63(RR-05):1-30.