



For further information,
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Human Papillomavirus (HPV) Quadrivalent Vaccine

The Clinical Prevention Initiative (CPI), a collaboration of the New Mexico Medical Society and the New Mexico Department of Health, and the New Mexico Immunization Coalition urge all medical practices and health professionals to routinely initiate a series of three injections of HPV Quadrivalent Vaccine (Gardasil[®] from Merck) to all females aged 11 and 12 years.

HPV infection is the most common sexually transmitted infection in the United States and causes a majority of atypical squamous cells of undetermined significance (ASCUS), more than 90% of all cervical intraepithelial neoplasia (CIN 1,2,3), and virtually all invasive cervical cancers. HPV vaccine is a recombinant product of highly purified virus-like particles of HPV capsid proteins produced in yeast consisting of four types of human papillomavirus: types 16 and 18, which cause approximately 70% of cervical cancers, and types 6 and 11, which are responsible for approximately 90% of genital warts.

Genital tract HPV DNA testing is not recommended to screen female patients for pre-existing HPV infections.

Who Should Receive HPV Vaccine

- * All adolescent females aged 11 and 12 years should receive a first dose of HPV vaccine and additional doses at 2 and 6 months after the first dose. Most females become infected with genital tract HPV shortly after sexual initiation. The vaccine is not effective after HPV infection has been acquired. Therefore, the HPV vaccine is most beneficial when provided before sexual activity begins.
- * At the discretion of the clinician, the series may be started in females as young as 9 years of age.
- * HPV vaccine may be considered for adolescent females and women between the ages of 13 and 26 years of age on a case-by-case basis.
- * The decreased effectiveness of the HPV vaccine in sexually experienced populations should be discussed with patients.
- * HPV vaccine is not currently recommended for administration to adolescent males or young adult men. Studies are in process and it is possible that in the future this vaccine will be recommended for males.

Giving HPV Vaccine with Other Vaccines

- * The HPV series can conveniently and safely be initiated in tandem with other vaccines. It is recommended (ACIP, AAFP, and AAP) to be given with the other vaccines for 11 and 12 year olds – the Meningococcal Conjugate (MCV4) and the Tetanus, Diphtheria, Pertussis (Tdap) booster.
- * HPV vaccine has been safely administered with Hepatitis B vaccine.

Side Effects

- * Local: injection site pain (84%), swelling (25%) and erythema (25%).
- * Systemic: low grade fever (10–13 %), nausea (4.2%) and dizziness (2.8%).

Contraindications

- * Previous allergic reactions to any of the vaccine constituents including aluminum hydroxyphosphate sulfate, L-histidine, and sodium borate.

Precautions

- * Successful completion of the HPV vaccine series does not change the recommendations for periodic screening with Pap smears.

Precautions (continued)

- * HPV vaccine is not recommended for use during pregnancy. If a recipient is determined pregnant, the series should be interrupted until after parturition. Merck maintains a Pregnancy Registry to monitor fetal outcomes of pregnant women exposed to Gardasil®. Patients and healthcare providers are encouraged to report any exposure to Gardasil® during pregnancy by calling (800) 986-8999.
- * The incidence of Caesarian section, pregnancy related problems, and congenital anomalies were equivalent in women receiving HPV vaccines or placebo.

How to Store and Administer the Vaccine

- * Refrigerate immediately upon arrival at 2 – 8° C (36 – 45° F). Do not freeze the vaccine.
- * The vaccine is provided in single dose 0.5 ml vials or pre-filled single dose syringes with a 25 gauge, 1” needle.
- * Three separate doses of vaccine should be administered IM - the initial, a second dose 2 months later, and a third dose 6 months after the initial.
- * IM deltoid preferred or the higher anterolateral area of the thigh.

How to Obtain the Vaccine

- * Vaccine may be ordered through the Vaccines for Children (VFC) program at the New Mexico Department of Health for all females 11 and 12 years old, and for selective catch-up vaccination for females ages 13-18 years. Use the VFC vaccine order form at <http://www.health.state.nm.us/immunize/forms/vaccineorder.pdf> and fax to 505-827-1741.
- * Vaccine for other age groups may be obtained at MerckVaccines.com or by calling 1-877-VAX-MERCK (1-877-629-6372).

Suggestions for Smooth Third Party Reimbursement

VFC (not purchased) Vaccine:

Vaccine is available free of charge through the VFC program for patients. No source can be billed for the vaccine acquired from VFC. Claims should show the vaccine code (90649) with a zero (\$0.00) charge and the administration fee code (90471 or 90472). The exception is the fee-for-service, exempt Medicaid (not SALUD!) program. For exempt Medicaid providers, use only the CPT code for the vaccine (90649) and enter the usual charge for vaccine administration. Use diagnosis code V05.8 for HPV vaccine and administration.

Non-VFC (purchased) Vaccine:

Please check with your patient’s insurance plan whether HPV is a covered benefit, if it falls under the deductible, and/or if prior authorization is required. It is customary to bill for vaccine and vaccine administration. We suggest you place CPT-4 modifier -25 after your evaluation and management code (99201-99215) to indicate the office visit was unrelated to administration of HPV vaccine. Use diagnosis code V05.8 for HPV vaccine and administration.

NM Statewide Immunization Information System (NMSIIS)

It is important for providers to enter immunization data directly into NMSIIS so that a child’s complete immunization history becomes available to any health professional who has access to the system. The proper utilization of NMSIIS helps to eliminate over-immunizing a child as well as to identify those who are under-immunized. To request NMSIIS training for your office, please contact the NM Department of Health at 1-800-280-1618.

For Further Information

Clinical Prevention Initiative at 505-828-0237 or 800-748-1596 or cpi@nmms.org

Centers for Disease Control and Prevention Vaccination Information Statement

<http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hpv.pdf>

New Mexico Department of Health HPV Administration Information

<http://www.health.state.nm.us/immunize/pages/provider/NMHPVGuidelines.pdf>