

Kentucky Statewide Physician Protocol for Human Papillomavirus (HPV) Vaccines

Purpose

This statewide physician protocol signed by a physician with the Kentucky Department for Medicaid Services specifies the criteria and procedures for eligible pharmacies to order and administer the Human papillomavirus vaccine to **eligible Medicaid beneficiaries**.

Disclaimer: This signed protocol is only intended for pharmacies that **do not** have a medical provider to issue a protocol and should **not** be used to order and administer a vaccine to **non-Medicaid** beneficiaries.

Human Papillomavirus Vaccine Protocol													
Background	<ul style="list-style-type: none"> Human Papillomavirus (HPV) is a common group of more than 150 related viruses that infect approximately 13 million teens and adults through intimate skin-to-skin contact annually. HPV may infect both males and females. Some HPV infections can lead to certain types of cancer. <ul style="list-style-type: none"> While most HPV infections go away on their own, some infections that don't go away can cause cervical, vaginal, and vulvar cancers in females; penile cancer in males; anal cancer; oropharyngeal cancer, and genital warts. Early vaccination may protect preteens before they are exposed to the virus. 												
Vaccine	<ul style="list-style-type: none"> Gardasil® 9 (Human Papillomavirus 0-valent Vaccine, Recombinant) Suspension for Intramuscular Injection 0.5-mL suspension for injection as a single-dose vial or prefilled syringe. 												
Vaccine Schedule	<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Age</th> <th>Regimen</th> <th>Schedule</th> </tr> </thead> <tbody> <tr> <td>9 through 14 years</td> <td>2- dose</td> <td>0, 6 to 12 months*</td> </tr> <tr> <td></td> <td>3- dose**</td> <td>0, 2, 6 months</td> </tr> <tr> <td>15 through 45 years</td> <td>3- dose</td> <td>0, 2, 6 months</td> </tr> </tbody> </table> <p>* If the second dose of a 2-dose series is administered earlier than 5 months after the first dose, administer a third dose at least 4 months after the second dose. ** Three doses are recommended for immunocompromised persons (including those with HIV infection) aged 9 through 14 years.</p>	Age	Regimen	Schedule	9 through 14 years	2- dose	0, 6 to 12 months*		3- dose**	0, 2, 6 months	15 through 45 years	3- dose	0, 2, 6 months
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Eligibility	<ul style="list-style-type: none"> Gardasil 9 is approved for females and males aged 9-45. <ul style="list-style-type: none"> Routine HPV vaccination is recommended at age 11 or 12. Catch-up HPV vaccination is recommended through age 26 for all persons not adequately vaccinated. Recommendations for HPV vaccination in adults aged 27-45 should be based on an informed decision-making process between the healthcare provider and the patient to assess the risk for new HPV infections and the possible benefits of vaccination. The HPV vaccine may be given simultaneously with all routine adolescent or adult vaccines. 												
Contraindications	<ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) to a previous dose or any vaccine component Hypersensitivity to yeast Pregnancy: HPV vaccines should not be administered during pregnancy. Exposure during pregnancy can be reported to Merck Sharp & Dohme LLC at 1-800-986-8999. 												
Warnings and Precautions	<ul style="list-style-type: none"> Vaccination of persons with moderate or severe acute illnesses should be deferred until symptoms improve. Syncope after immunization is common among adolescents. It is recommended patients sit for 15 minutes after vaccination. 												

Side Effects and Adverse Reactions	<ul style="list-style-type: none"> • Injection Site Reactions- pain, redness, or swelling at the vaccination site (up to 90%) • Low-grade fever of up to 101° F (up to 10%) • Fever of 102° F or more (up to 1.5%)
Storage and Handling	<ul style="list-style-type: none"> • Store refrigerated at 2 to 8°C (36 to 46°F). • Do not freeze. • Protect from light. • Administer as soon as possible after being removed from refrigeration.
Education	<ul style="list-style-type: none"> • Pharmacy employees are trained in the proper administration, storage, and handling of Human Papillomavirus Vaccines. • Pharmacy employees have reviewed manufacturer instructions. • Pharmacy employees should educate their patients about the vaccine using the respective Vaccine Information Statement (VIS) • All pharmacists, pharmacist interns, and pharmacy technicians may administer vaccines to children age 9 and above under this protocol pursuant to meeting the requirements set forth by 201 KAR 2:420 - Administration of vaccines
Documentation	<ul style="list-style-type: none"> • Pharmacy employees must comply with recordkeeping and reporting requirements as required by the Kentucky Board of Pharmacy. • For off-site administration, pharmacy employees must document vaccine administration in their dispensing system within 24 hours of administration. • Pharmacy employees should report the administration of each vaccination to the Kentucky Immunization Registry (KYIR) within 72 hours.

HPV Vaccine Statewide Physician Protocol Signature[‡]:

Judith Ann Theriot, MD electronic

August 26, 2024

Judith Ann Theriot, MD
Medical Director
Kentucky Department Medicaid Services
National Provider ID: 1811990476

Date Signed

[‡] ***This signed protocol must be renewed annually.***