GARDASIL®9
Human Papillomavirus
9-valent Vaccine, Recombinant

December 2015

Product Update

GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

Dear Customer,

Merck is pleased to announce that the US Food and Drug Administration (FDA) has approved an expanded age indication for GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant), Merck's 9-valent human papillomavirus (HPV) vaccine, to now include use in males 16 through 26 years of age. This indication is a key milestone in transitioning from GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] to GARDASIL 9 in the United States. Merck will continue to communicate with customers during this transition to ensure the appropriate availability of each product.

During its February 2015 meeting, the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) voted to include GARDASIL 9 in the recommendations for use of HPV vaccines. GARDASIL 9 was added to the routine recommendations for vaccination of 11- and 12-year-old females and males. At that time, the ACIP also added recommendations for GARDASIL 9 for females aged 13 to 26 and for males aged 13 to 21 who have not been vaccinated previously or have not completed the 3-dose series.[1]

GARDASIL 9 is supplied in 0.5-mL single-dose vials and prefilled syringes. For your convenience, the packaging, CPT® code, NDC number, and pricing information are listed below. This information has not been changed.

HOW SUPPLIED	PACKAGING	CPT® CODE[2]	NDC NUMBER	CATALOG PRICE (CARTON OF 10)	CATALOG PRICE (PER DOSE)
GARDASIL 9 0.5-mL suspension	Carton of ten 0.5 mL single-dose vials	90651	00006-4119-03	$1,769.54	$176.95
GARDASIL 9 0.5-mL suspension	Carton of ten 0.5 mL single-dose prefilled Luer-Lock syringes with tip caps	90651	00006-4121-02	$1,784.68	$178.47

Please read the accompanying press release for GARDASIL 9 announcing the updated indication.

IMPORTANT INFORMATION ABOUT *GARDASIL 9*

Indication

GARDASIL 9 is a vaccine indicated in females 9 through 26 years of age for the prevention of cervical, vulvar, vaginal, and anal cancers caused by human papillomavirus (HPV) Types 16, 18, 31, 33, 45, 52, and 58; precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58; and genital warts caused by HPV Types 6 and 11.

GARDASIL 9 is indicated in males 9 through 26 years of age for the prevention of anal cancer caused by HPV Types 16, 18, 31, 33, 45, 52, and 58; precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58; and genital warts caused by HPV Types 6 and 11.

GARDASIL 9 does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening. Recipients of GARDASIL 9 should not discontinue anal cancer screening if it has been recommended by a health care professional.

(IMPORTANT INFORMATION ABOUT *GARDASIL 9* CONTINUES ON NEXT PAGE)

MERCK

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IMPORTANT INFORMATION ABOUT *GARDASIL 9 (continued)*

GARDASIL 9 has not been demonstrated to provide protection against diseases from vaccine HPV types to which a person has previously been exposed through sexual activity.

GARDASIL 9 is not a treatment for external genital lesions; cervical, vulvar, vaginal, and anal cancers; or cervical intraepithelial neoplasia (CIN), vulvar intraepithelial neoplasia (VIN), vaginal intraepithelial neoplasia (VaIN), or anal intraepithelial neoplasia (AIN).

Not all vulvar, vaginal, and anal cancers are caused by HPV, and GARDASIL 9 protects only against those vulvar, vaginal, and anal cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58.

Vaccination with GARDASIL 9 may not result in protection in all vaccine recipients.

Select Safety Information

GARDASIL 9 is contraindicated in individuals with hypersensitivity, including severe allergic reactions to yeast, or after a previous dose of GARDASIL 9 or GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant].

Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion.

Safety and effectiveness of GARDASIL 9 have not been established in pregnant women.

The most common (≥10%) local and systemic adverse reactions in females were injection-site pain, swelling, erythema, and headache. The most common (≥10%) local and systemic reactions in males were injection-site pain, swelling, and erythema.

Dosage and Administration

GARDASIL 9 should be administered intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh at the following schedule: 0, 2 months, 6 months.

Before administering GARDASIL 9, please read the accompanying Prescribing Information. The Patient Information also is available.

If you have any questions regarding GARDASIL 9, please contact your Merck Representative or Account Executive.

Sincerely,

Colleen McGuffin
Vice President, Customer & U.S. Commercial Operations

Reference: 1. Centers for Disease Control and Prevention (CDC). Use of 9-valent Human Papillomavirus (HPV) Vaccine: Updated HPV Vaccination Recommendations of the Advisory Committee on Immunization Practices. *MMWR Morb Mortal Wkly Rep*. 2015;64(11):300–304.**2.** CPT© Category I Vaccine Codes. American Medical Association Web site. https://download.ama-assn.org/resources/doc/cpt/x-pub/vaccine-code-desc.pdf.pdf. Updated July 23, 2015. Accessed November 24, 2015.

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