Billing Codes and National Drug Codes (NDCs) for GARDASIL®9

INDICATION

- GARDASIL 9 is a vaccine indicated in females 9 through 45 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 45 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.

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].

GARDASIL®9

Human Papillomavirus 9-valent Vaccine, Recombinant

Indication and Select Safety Information continued on next pages.

BILLING CODES

Below are lists of codes that may be relevant for GARDASIL 9 and its administration. This information is current as of October 2018. The information provided here is compiled from sources believed to be accurate, but Merck makes no representation that it is accurate. Consult the relevant manual and/or other guidelines for a description of each code to determine the appropriateness of a particular code and for information on additional codes. This information is subject to change. Merck cautions that payer coding requirements vary and can frequently change, so it is important to regularly check with each payer as to payer-specific requirements. You are solely responsible for determining the appropriate codes and for any action you take in billing. The information provided here is not intended to be definitive or exhaustive, and is not intended to replace the guidance of a qualified professional advisor. Merck and its agents make no warranties or guarantees, expressed or implied, concerning the accuracy or appropriateness of this information for your particular use given the frequent changes in public and private payer billing. The use of this information does not guarantee payment or that any payment received will cover your costs. Diagnosis codes should be selected only by a health care professional.

NDC AND PACKAGING INFORMATION

PRODUCT	PACKAGE	NDC
GARDASIL® 9 (Human Papillomavirus 9-valent Vaccine, Recombinant)	Carton of ten 0.5-mL single-dose vials	0006-4119-03
	Carton of ten 0.5-mL single-dose prefilled Luer Lock syringes with tip caps	0006-4121-02

Please note: The NDC above is the billable NDC that appears on the carton. The NDC on the vial should not be used for billing purposes.

Below are codes that might be relevant when submitting a claim for GARDASIL 9. Please consult with the applicable payer to understand the payer's specific billing requirements.

INDICATION (*continued*)

- GARDASIL 9 does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening.

SELECT SAFETY INFORMATION (*continued*)

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.

Indication continued on next pages.

GARDASIL® 9
Human Papillomavirus
9-valent Vaccine, Recombinant

DIAGNOSIS CODE*

ICD-10-CM CODE	DESCRIPTOR
Z23	Encounter for immunization

*ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification. Centers for Disease Control and Prevention. 2019 Release of ICD-10-CM. https://www.cdc.gov/nchs/icd/icd10cm.htm. Accessed October 15, 2018.

CPT CODES†

CPT CODES FOR VACCINE ADMINISTRATION	DESCRIPTOR
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)
90472	Each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure) (Use in conjunction with 90460, 90471, or 90473)
CPT CODE FOR *GARDASIL 9*	**DESCRIPTOR**
90651	Human Papillomavirus vaccine types 6, 11, 16, 18, 31, 33, 45, 52, 58, nonavalent (9vHPV), 2 or 3 dose schedule, for intramuscular use

†CPT=Current Procedural Terminology. CPT Copyright © 2017. American Medical Association. All rights reserved. CPT® is a registered trademark of American Medical Association.

INDICATION (*continued*)

- Recipients of GARDASIL 9 should not discontinue anal cancer screening if it has been recommended by a health care professional.
- 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.

GARDASIL® 9
Human Papillomavirus
9-valent Vaccine, Recombinant

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.
  - For individuals 9 through 14 years of age, GARDASIL 9 can be administered using a 2-dose or 3-dose schedule. For the 2-dose schedule, the second dose should be administered 6–12 months after the first dose. If the second dose is administered less than 5 months after the first dose, a third dose should be given at least 4 months after the second dose. For the 3-dose schedule, GARDASIL 9 should be administered at 0, 2 months, and 6 months.
  - For individuals 15 through 45 years of age, GARDASIL 9 is administered using a 3-dose schedule at 0, 2 months, and 6 months.

Before administering GARDASIL 9, please read the accompanying Prescribing Information.
The Patient Information also is available. For additional copies of the Prescribing Information, please call 800-672-6372, visit gardasil9.com, or contact your Merck representative.

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Human Papillomavirus
9-valent Vaccine, Recombinant