

MedStar Health, Inc.

POLICY AND PROCEDURE MANUAL

Policy Number: MP.033.MH
Last Review Date: 02/21/2019
Effective Date: 04/01/2019

MP.033.MH – HPV Vaccine

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **HPV Vaccine** medically necessary for the following indications:

Quadriant HPV Vaccine (Gardasil) is indicated:

1. For girls and women who are between the age of 9 and 26 for prevention of the following disease caused by HPV types included in the vaccine:

- Cervical, vulvar, vaginal and anal cancer caused by HPV types 16 and 18
- Genital warts caused by HPV types 6 and 11

And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, and 18:

- Cervical adenocarcinoma in situ (AIS) and Cervical intraepithelial neoplasia (CIN) grade 2/3
- Cervical intraepithelial neoplasia (CIN) grade 1
- Vulvar intraepithelial neoplasia (VIN) grade 2 and 3
- Vaginal intraepithelial neoplasia (VAIN) grade 2 and 3
- Anal intraepithelial neoplasia (AIN) grades 1, 2, and 3

2. It is recommended that it be routinely given to girls 11-12 years old as a preventive service against cervical cancer.

- The vaccine is administered in three separate intramuscular injections over a six month period.
- It is recommended that the second dose be administered two months after the first dose and the third dose six months after the first dose.

3. For boys and men who are between the age of 9 and 26 for routine prevention of HPV and prevention of genital warts caused by HPV.

GARDASIL 9 is indicated:

1. For girls and women who are between the age of 9 and 26 for prevention of the following disease caused by HPV types included in the vaccine:

- Cervical, vulvar, vaginal and anal cancer caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58;

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- Genital warts caused by HPV types 6 and 11
And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58
- 2. For boys and men 9 through 26 years of age for routine prevention of HPV and prevention of genital warts caused by HPV:
 - a. Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52
 - b. Genital warts caused by HPV types 6 and 11.
 - c. And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, 58
- 3. It is recommended that GARDASIL 9 should be administered intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh:
 - a. For individuals 9 through 14 years of age, GARDASIL 9 can be administered using a 2-dose or 3-dose schedule.
 - i. 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.
 - ii. For the 3-dose schedule, GARDASIL 9 should be administered at 0, 2 months, and 6 months.
 - b. For individuals 15 through 26 years of age, GARDASIL 9 is administered using a 3-dose schedule at 0, 2 months, and 6 months.

LIMITATIONS - Gardasil:

- Gardasil is contraindicated in individuals who are hypersensitive to the active substances or to any of the excipients of the vaccine.
- It is not recommended to be given during pregnancy.
- If pregnancy is detected after vaccination has been given, the subsequent dosing should be delayed until the pregnancy has been completed.
- The vaccine does not replace routine cervical cancer screening as per national guidelines for screening.

Bivalent HPV vaccine (Cervarix) is indicated:

1. For girls and women between the age of 9 and 25 for the prevention of the following diseases caused by oncogenic HPV types 16 and 18:
 - Cervical cancer
 - Cervical intraepithelial neoplasia (CIN) grade 2 or worse and adenocarcinoma in situ **AND**
 - Cervical intraepithelial neoplasia (CIN) grade 1

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2. Administration:

- The vaccine is administered in three separate intramuscular injections over a six month period according to the following schedule: 0, 1-2, and 6 months

Coverage is also provided for those vaccines that are FDA approved for the prevention of anal cancer and associated precancerous lesions due to HPV types 16 and 18 in people ages 9 through 26 years.

Limitations

Cervarix:

1. It does not provide protection against disease due to all HPV types
2. It has not been demonstrated to provide protection against disease from vaccine and non-vaccine HPV types to which a woman has previously been exposed through sexual activity.

Background

The US Preventive Services Task Force (USPSTF) reports an age-adjusted annual incidence rate of cervical cancer to be 6.6 cases per 100,000 women. It most commonly occurs in women 35-55 years of age and is the second most common cancer in women worldwide. Cervical cancer deaths have decreased dramatically in the United States since the implementation of more widespread cervical cancer screening.

The Mayo Clinic defines the Human Papillomavirus (HPV) Test as a test that detects the presence of HPV, a virus that can lead to the development of genital warts, abnormal cervical cells and cervical cancer. Scientists have identified over 80 HPV types, with about 40 types affecting the genital tract. Currently, the HPV test only exists to women.

The CDC details the three license HPV vaccines available in the United States:

- Gardasil 9: FDA approved Gardasil 9 for use in 2014. The safety of Gardasil 9 was studied in clinical trials with more than 15,000 participants before it was licensed and continues to be monitored. Gardasil 9 protects against HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58.
- Gardasil: FDA approved Gardasil for use in 2006. The safety of Gardasil was studied in clinical trials with more than 29,000 participants before it was licensed and continues to be monitored. Gardasil protects against HPV types 6, 11, 16, and 18. Gardasil has been shown to prevent anal, vulvar, and vaginal cancers related to 2 types of HPV.
- Cervarix: FDA approved Cervarix for use in 2009. The safety of Cervarix was studied in clinical trials with more than 30,000 participants before it was licensed and continues to be monitored. Cervarix protects women and girls against HPV types 16 and 18.

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Codes:

CPT Codes / HCPCS Codes / ICD-10 Codes	
Code	Description
CPT codes:	
90649	Human Papilloma virus (HPV) vaccine, types 6, 11, 16, 18 (quadrivalent), 3 dose schedule, for intramuscular use.
90650	Human Papilloma virus (HPV) vaccine, types 16, 18, (bivalent), 3 dose schedule, for intramuscular use
90651	Human Papilloma virus (HPV) vaccine, types 6, 11, 16, 18, 31, 33, 45, 52, 58 nonvalent (HPV), 3 dose schedule, for IM use
ICD-10 codes covered if selection criteria are met:	
Z23	Encounter for Immunization

References

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2. Centers for Disease Control and Prevention: Use of a 2-Dose Schedule for HPV Vaccination – Updated Recommendations of the Advisory Committee on Immunization Practices. December 16, 2016. Reviewed: August 14, 2007 <https://www.cdc.gov/mmwr/volumes/65/wr/mm6549a5.htm>
3. Centers for Disease Control and Prevention: Vaccine information statement-HPV, Updated December 2, 2016. <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/hpv.pdf>
4. Centers for Disease Control and Prevention: Human papillomavirus (HPV)-HPV vaccines, Updated August 23, 2018. <http://www.cdc.gov/hpv/vaccine.html>
5. Centers for Disease Control and Prevention: Morbidity and Mortality Weekly Report - Use of 9-Valent Human Papillomavirus (HPV) Vaccine: Updated HPV Vaccination Recommendations of the Advisory Committee on Immunization Practices. Updated March 27, 2015. <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a3.htm>
6. GlaxoSmithKline: Cervarix-human papillomavirus vaccine types 16 and 18 (Recombinant, A504 adjuvanted), Updated May 30, 2016. https://au.gsk.com/media/324141/cervarix-pi_012_approved.pdf
7. Hayes Medical Technology Directory. Human Papillomavirus Vaccines for Prevention of Cervical Cancer. Annual Review June 25, 2010. Archived Oct 25, 2011
8. Hayes News – Government. FDA Approves Two-Dose Gardasil 9 Regimen. October 14, 2016.

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10. Merck: Gardasil-9 Human Papillomavirus 9-valent Vaccine, Recombinant. <https://www.merckvaccines.com/Products/Gardasil9>
11. U.S. Food & Drug Administration (FDA). Approval Letter – Gardasil. April 5, 2011. Updated February 5, 2018
<https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm094042.htm>
12. U.S. Food & Drug Administration (FDA). Approval Letter – Cervarix. July 19, 2011. Updated February 26, 2018
<https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm186957.htm>
13. U.S. Food & Drug Administration (FDA). Approved Products. FDA Information on Gardasil - Presence of DNA Fragments Expected, No Safety Risk. October 21, 2011.
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm276859.htm>
14. U.S. Food & Drug Administration (FDA). Approved Products. Gardasil 9. October 10, 2018.
<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm426445.htm>

Disclaimer:

MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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