Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy
Gardasil® is COVERED for the FDA approved indications for female and male members between the ages of 9 and 26.

Gardasil 9® is COVERED for the FDA approved indications for female and male members between the ages of 9 and 26.

Cervarix® is COVERED for the FDA approved indications for female members between the ages of 9 and 26.

Human papillomavirus (HPV) vaccine is NOT COVERED for adults 27 years of age or older and children younger than 9.

Description
Human papillomavirus (HPV) is a family of very common viruses that cause almost all cervical cancers, plus a variety of other problems like common warts, genital warts and plantar warts. HPV also causes cancers of the vulva, vagina, anus, cancers of the head and neck, as well as other cancers and precancerous lesions. Women and men become infected with HPV types that cause cervical cancer through sexual intercourse and sexual contact. Most women and men will be exposed to HPV during their lifetime.

An HPV infection rarely leads to cervical cancer. In most women, the cells in the cervix return to normal after the body's immune system destroys the HPV infection. However, some HPV infections do not go away and may remain present in the cervical cells for years. Long-standing infection can lead to changes in the cells that can progress to cancer.

FDA Approval
In June 2006, the U.S. Food and Drug Administration (FDA) approved Gardasil®, a vaccine to prevent cervical cancer and genital warts caused by certain types of HPV. Gardasil® is a quadrivalent human papillomavirus vaccine produced using recombinant DNA techniques. It targets HPV types 16 and 18 that are associated with an estimated 70% of cervical cancers and high-grade cervical intraepithelial neoplasia (CIN) as well as types 6 and 11 that are associated with 90% of genital warts. The vaccine was licensed for use in girls and women ages 9-26 years.
In October 2009, the U.S. Food and Drug Administration (FDA) approved Cervarix®, a vaccine to prevent cervical cancer and genital warts caused by certain types of HPV. Cervarix® is a bivalent human papillomavirus vaccine
produced using recombinant DNA techniques. It targets HPV types 16 and 18 that are associated with an estimated 70% of cervical cancers and high-grade cervical intraepithelial neoplasia (CIN). The vaccine was licensed for use in girls and women ages 10-25 years.

In October 2009, the U.S. Food and Drug Administration (FDA) approved use of the vaccine Gardasil® for the prevention of genital warts (condyloma acuminata) due to human papillomavirus (HPV) types 6 and 11 in boys and men, ages 9 through 26.

In December 2010, the U.S. Food and Drug Administration (FDA) approved use of the vaccine Gardasil® for the prevention of anal cancer in both males and females ages 9 through 26.

In December 2014, U.S. Food and Drug Administration (FDA) approved GARDASIL® 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) vaccine, for use in girls and young women 9 to 26 years of age for the prevention of cervical, vulvar, vaginal, and anal cancers caused by HPV types 16, 18, 31, 33, 45, 52 and 58, pre-cancerous 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 also approved for use in boys 9 to 15 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.

The human papillomavirus vaccine is recommended by the Advisory Committee on Immunization Practices (ACIP) of the U.S. Department of Health and Human Services/Centers for Disease Control and Prevention. The ACIP recommends a 3-dose schedule with the second and third doses administered 2 and 6 months after the first dose. Routine vaccination with HPV is recommended for females aged 11--12 years; the vaccination series can be started in females as young as age 9 years; and a catchup vaccination is recommended for females aged 13--26 years who have not been vaccinated previously or who have not completed the full vaccine series. ACIP recommends routine vaccination of males aged 11 or 12 years with HPV4 administered as a 3-dose series. The vaccination series can be started beginning at age 9 years. Vaccination with HPV4 is recommended for males aged 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series. Males aged 22 through 26 years may be vaccinated.

**Prior Authorization**

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement. (denial)

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met. (split)

**Coding Considerations**

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

**CPT Codes**

90649 - Human Papilloma virus (HPV) vaccine, types 6, 11, 16, 18 (quadrivalent), 3 dose schedule, for intramuscular use. Includes Gardasil.

90650 - Human Papilloma virus (HPV) vaccine, types 16, 18 (bivalent), 3 dose schedule, for intramuscular use. Includes Cervarix.

90651 - Human Papilloma virus (HPV) vaccine, types 6, 11, 16, 18, 31, 33, 45, 52, 58 (9-valent), 3 dose schedule, for intramuscular use. Includes Gardasil 9.

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Re-Review Date(s): 4/21/2011, 5/1/14, 4/28/16, 9/27/16

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