

Policy: MP228

Section: Medical Benefit Policy

Subject: Human Papillomavirus (HPV) DNA Testing

Applicable Lines of Business

Commercial	X	CHIP	X
Medicare	X	ACA	X
Medicaid	X		

I. Policy: Human Papillomavirus (HPV) DNA Testing

II. Purpose/Objective:

To provide a policy of coverage regarding Human Papillomavirus (HPV) DNA Testing

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

The human papillomavirus (HPV) DNA test is done on a sample of cells collected from the cervix and checks for the genetic material of the human papillomavirus. The test is used to identify whether a high-risk type of HPV (types 16, 18, 31, and 45) is present.

INDICATIONS:

1. The assessment of members at any age when a Pap smear detects:
 - Atypical squamous cells of undetermined significance (ASCUS); or
 - Low-grade squamous intraepithelial (LSIL) cells
2. As a cervical cancer screening option when used alone or in combination with a Pap smear or liquid-based cytology in members aged 30 years and older according to US Preventive Services Task Force (USPSTF) recommendations.

EXCLUSIONS:

- Use as a primary screening test option in members younger than 30 years of age
- Use when positive cervical cytology has been definitively identified

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, will be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Human Papillomavirus (HPV) DNA Testing

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 87624 Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), high-risk types (eg, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)
- 87623 Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), low-risk types (eg, 6, 11, 42, 43, 44)
- 87625 Infectious agent detection by nucleic acid (DNA or RNA); Human Papillomavirus (HPV), types 16 and 18 only, includes type 45, if performed
- G0476 Infectious agent detection by nucleic acid (DNA or RNA); human papillomavirus HPV), high-risk types (e.g., 16, 18, 31, 35, 39, 45, 51, 52, 56, 58, 59, 68) for cervical cancer screening, must be performed in addition to pap test
- 0096U Human papillomavirus (HPV) high risk types (ie,16,18,31,33,35,39,45,51,52,56,58,59,66,68), male urine

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Cuzick J, Clavel C, Petry KU, Meijer CJLM, Hoyer H, Ratnam S, et al. Overview of the European and North American studies on HPV testing in primary cervical cancer screening. Int J Cancer.2006;119:1095-1101.

Mayrand M-H, Duarte-Franco E, Coutlee F, Rodrigues I, Walter SD, Ratnam S, et al. Randomized controlled trial of human papillomavirus testing versus Pap cytology in the primary screening for cervical cancer precursors: Design, methods and preliminary accrual results of the Canadian cervical cancer screening trial (CCCaST). *Int J Cancer*. 2006;119:615-623.

Mayrand MH, Duarte-Franco E, Rodrigues I, Walter SD, Hanley J, Ferenczy A, et al.; Canadian Cervical Cancer Screening Trial Study Group. Human papillomavirus DNA versus Papanicolaou screening tests for cervical cancer. *NEJM*. 2007 Oct 18;357(16):1579-1588.

Ronco G, Segnan N, Giorgi-Rossi P, Zappa M, Casadei GP, Carozzi F, et al. Human Papillomavirus Testing and Liquid-Based Cytology: Results at Recruitment From the New Technologies for Cervical Cancer Randomized Controlled Trial. *J Natl Cancer Inst*. 2006;98:765-774.

Naucler P, Ryd W, Tomberg S, Strand A, Wadell G, Elfgrén K et al. Human papillomavirus and Papanicolaou tests to screen for cervical cancer. *NEJM* 2007 Oct 18;357(16):1589-1597.

Naucler P, Ryd W, Tomberg S et al. Efficacy of HPV DNA testing with cytology triage and/or repeat HPV DNA testing in primary cervical cancer screening. *J Natl Cancer Inst*. 2009;101(2):88-99.

Hayes Inc Online. Hybrid Capture HPV Testing for Cervical Cancer. Updated 2/14/08.

ECRI Institute. HTAIS. HPV DNA test and revised guidelines are gaining acceptance for cervical cancer screening. 5/1/04

ECRI Institute. HTAIS Human papillomavirus (HPV) DNA testing for assessing cervical cancer risk. Dec. 1999.

Farag R, Redline R, Abdul-Karim FW. Value of combining HPV-DNA testing with follow-up papanicolaou smear in patients with prior atypical squamous cells of undetermined significance. *Acta Cytol* 2008;52:294-296.

Ronco G, Giorgi-Rossi P, Carozzi F et al. Results at recruitment from a randomized controlled trial comparing human papillomavirus testing alone with conventional cytology as the primary cervical cancer screening test. *J Natl Cancer Inst* 2008;100(7):492-501.

Castle PE, Fetterman B, Poitras N, et al. Five-year experience of human papillomavirus DNA and papnicolaou test cotesting. *Obstetrics & Gynecology* 2009;113(3):595-600.

Institute for Clinical Systems Improvement. Technology Assessment Report: HPV DNA testing for the screening and monitoring of cervical cancer. Oct. 2005.

American Society for Colposcopy and Cervical Pathology. 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests. <http://download.journals.elsevierhealth.com/pdfs/journals/0002-9378/PIIS0002937807009301.pdf>

US Preventive Services Task Force. Screening for Cervical Cancer Recommendations and Rationale. <http://www.ahrq.gov/clinic/3rduspstf/cervcan/cervcanrr.htm>

American Society of Cytopathology. ASC Statement on New Technologies in Cervical Cytology Screening. <http://www.cytopathology.org/website/article.asp?id=10>

American Cancer Society. Cervical Cancer: Prevention and Early Detection http://www.cancer.org/docroot/CRI/content/CRI_2_6x_cervical_cancer_prevention_and_early_detection_8.asp?sitearea=PED

Elfström KM, et al. Long-term HPV type-specific risks for ASCUS and LSIL: a 14-year follow-up of a randomized primary HPV screening trial. *Int J Cancer* 2015 Jan 15;136(2):350-9.

Smelov V, et al. Long-term HPV type-specific risks of high-grade cervical intraepithelial lesions: a 14-year follow-up of a randomized primary HPV screening trial. *Int J Cancer* 2015 Mar 1;136(5):1171-80.

JAMA. Screening for Cervical Cancer US Preventive Services Task Force Recommendation Statement.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 04/06/09

Revised: 7/16 (Gender Language), 8/22 (revise coverage options)

Reviewed: 05/10, 5/11, 5/12, 5/13, 5/14, 5/15, 5/16, 4/17, 4/18, 4/19, 4/20, 4/21, 4/22

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.