



Subject: *Human Papilloma Virus (HPV) DNA testing*

Number: *200312-0005*

Effective date: 12/22/2003

Revision date(s): 12/2000, 06/2003, 12/17/2003

Important note

Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the *Evidence of Coverage* to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy and Criteria Statement. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. The Centers for Medicare and Medicaid's *Coverage Issues Manual* can be found on the following Web site:
<http://www.cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp>.

Overview

Human papilloma virus (HPV) is a common sexually transmitted disease. This virus can cause changes in the cervix which may be pre-cancerous, which could then progress to cervical cancer. Only certain types of HPV are known to cause cancer.

To determine if HPV is present on a sample of cervix (Pap smear), and to determine which type of HPV is present, a variety of tests could be used. They all test for the genetic code, or DNA, of the HPV virus.

Policy and criteria

NOTE: These services require prior authorization by the plan medical director.

When services are covered:

We cover **HPV DNA testing** when *any* of the following indications are met:

- For the assessment of women with
 - ASCUS (atypical squamous cells of undetermined significance); *or*
 - Low-grade squamous intraepithelial (LSIL) cells detected upon initial Pap smear.
- In combination with a Pap smear for screening women aged 30 years and older.

Note: Women who receive negative results on both tests should be rescreened no more frequently than every three years.

This policy is consistent with the National Cancer Institute's interim guidelines for managing abnormal cervical cytology, the position of the American Society of Colposcopy and Cervical Pathology for the management of ASCUS, and guidelines from the American College of Obstetricians and Gynecologists.

When services are not covered:

We **do not cover** services when the above criteria are not met or for any procedures or devices not listed above.

We **do not cover** services when used as a **primary screening test** for cervical cancer in women younger than 30 years of age. As per the U.S. Preventive Services Task Force (2003), the medical literature does not support HPV testing as a screening test for cervical cancer for younger individuals whose cervical cytology is normal or is unknown.

We **do not cover** services when *any* of the following contraindications exist:

- Definitely positive cervical cytology
- Patient is pregnant

Codes:

Codes	Number	Description
CPT	87620	Papillomavirus, human, direct probe technique
	87621	Papillomavirus, human, amplified probe technique
HCPCS	Not applicable	

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FCHP products to which this policy applies:

- ⊕ FCHP Direct and FCHP Select Care (HMO)
- ⊕ FCHP Flex Care Direct and Select (POS)
- ⊕ Fallon Preferred Care (PPO)
- ⊕ FCHP MassHealth
- ⊕ Non-Group: FCHP Independent Care, Direct enrollment and Bill-at-home
- ⊕ Medicare plan – *reminder* to refer to CMS for policy and criteria

References

1. American College of Obstetricians and Gynecologists, Committee on Gynecologic Practice. New Pap test screening techniques. Committee Opinion No. 206. Washington, DC: ACOG; August 1998.
2. American College of Obstetricians and Gynecologists, Committee on Gynecologic Practice. Cervical cytology screening. ACOG Technology Assessment in Obstetrics and Gynecology. No. 2. Washington, DC: ACOG; December 2002.
3. American College of Obstetricians and Gynecologists, Committee on Practice Bulletins – Gynecology. Cervical cytology screening. ACOG Practice Bulletin No. 45. Washington, DC: ACOG; August 2003.
4. American College of Obstetricians and Gynecologists. Diagnosis and treatment of cervical carcinomas. ACOG Practice Bulletin. Clinical Management Guidelines for Obstetrician-Gynecologists No. 35. Washington, DC: ACOG; May 2002.
5. American College of Obstetricians and Gynecologists. Guidelines for Women's Health Care. Washington, DC: ACOG; 1996:150-152.
6. American College of Preventive Medicine. Cervical cancer screening. Am J Prev Med. 1996;12(5):342-344.
7. American Society for Colposcopy and Cervical Pathology (ASCCP) Practice Guideline. Management guidelines for follow-up of atypical squamous cells of undetermined significance (ASCUS). Colposcopist 1996;27:1-9.
8. Bowman MA. Editors Comment. Cost-effectiveness of the conventional Papanicolaou test with a new adjunct to cytological screening for squamous cell carcinoma of the uterine cervix and its precursors. Arch Fam Med. 2000;9(8).
9. Centers for Disease Control and Prevention (CDC), National Center for Chronic Disease Prevention and Health Promotion. Cervical cancer and Pap test information. The National Breast and Cervical Cancer Early Detection Program. Atlanta, GA: CDC; updated May 31, 2002.
10. Cox JT, Massad LS, Lonky N, et al. Management guidelines for the follow-up of cytology read as low grade squamous intraepithelial lesion. J Lower Genital Tract Dis. 2000;4(2):83-92.

11. Cox JT. Evaluating the role of HPV Testing for Women with Equivocal Papanicolaou Test Findings. JAMA 1999;281(17):1645-1647.
12. Hayes, Winifred S. Technology Report. Hybrid Capture HPV Testing for Cervical Cancer. August 1999. Updated August 2002.
13. Hoffman MS, Cavanaugh D. Cervical cancer: screening and prevention of invasive disease. Cancer Control J. 1995;2(6):503-509.
14. Institute for Clinical Systems Improvement. HPV DNA Testing for Cervical Cancer. ICSI Healthcare Guideline. June 2001. Updated 04/25/2002
15. Institute for Clinical Systems Improvement. Cervical cancer screening. ICSI Healthcare Guideline. June 2002.
16. Koss LG. Human Papillomavirus Testing as a Screening Tool for Cervical Cancer. JAMA 2000;283 (19):2525-2526.
17. Liaw KL, Glass AG, Manos MM, et al. Detection of human papillomavirus DNA in cytologically normal women and subsequent cervical squamous intraepithelial lesions. J Natl Cancer Institute 1999;91(11): 954-960.
18. Manos MM, Kinney WK, Hurley LB, et al. Identifying women with cervical neoplasia: using human papillomavirus DNA testing for equivocal Papanicolaou results. JAMA 1999;281(17):1605-1610.
19. National Cancer Institute – Press Releases: HPV Testing May Be Useful in Cervical Cancer Screening (01/24/00), and HPV Testing Proves Sensitive in Identifying ASCUS Abnormalities That May Lead to Cervical Cancer (03/23/00)
20. National Institute of Health Consensus Development Panel. Cervical cancer. NIH Consensus Statement. Bethesda, MD: NIH; 1996;14(1):1-38.
21. Nobbenhuis MA, Walboomers JM, Helmerhorst TJ, et al. Relation of human papillomavirus status to cervical lesions and consequences for cervical-cancer screening: a prospective study. Lancet 1999; 354(9172):20-25.
22. Sherman ME, Lorincz AT, Scott DR, et al. Baseline cytology, human papillomavirus testing, and risk for cervical neoplasia: A 10-year cohort analysis. J Natl Cancer Inst. 2003;95:46–52.
23. U.S. Preventive Services Task Force. Screening for cervical cancer. In: Guide to Clinical Preventive Services. Report of the U.S. Preventive Services Task Force. 3rd ed. Rockville, MD: Agency for Healthcare Research and Quality: 2003.
24. Wright TC Jr, Cox JT, Massad LS, Twiggs LB, Wilkinson EJ. 2001 Consensus Guidelines for the management of women with cervical cytological abnormalities. JAMA. 2002;287:2120–2129.

Mandated benefit/Regulatory issues

- Federal
- Commonwealth of Massachusetts
- Medicare – National policy
- Medicare – Local medical review policy
- Not applicable

Committee review dates

Technology Assessment Committee: 12/2000, mm/yyyy

Utilization Management Committee: 06/2003, mm/yyyy

Approved by: <i>Signature on file</i>	12/18/2003
Dennis A. Batey, M.D., Vice President and Chief Medical Officer	Date