



Subject: *Pap Smear/Cervical Cancer Screening*

Number: *200510-0003*

Effective date:

Revision date(s): 10/04/05

Important note

Not all services are covered for all commercial products or employer groups. 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 & 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. CMS's Coverage Issues Manual can be found on the following Web site: <http://cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp>

Overview

It is widely recognized that cervical cancer screening is one of the most effective cancer screening tests reported to date. In countries where regular cervical screening is performed, rates of cervical cancer have demonstrated a dramatic decrease. Chapter 176G, § 4 and Chapter 175 § 47G of the General Laws of Massachusetts, mandate coverage for annual cytologic screening for women, eighteen years of age and older.

Policy

The plan covers cervical cancer screening using FDA approved techniques, either the conventional Pap smear or liquid based monolayer slide preparation (ThinPrep[®] or SurePath[®]) method. The decision regarding which method to use is at the clinical discretion of the attending physician. In accordance with the position statement of The American College of Obstetricians and Gynecologists, FCHP does not endorse the use of liquid based method over the conventional method.

Covered services

1. Medical office visit with a network provider
2. Cervical cancer screening once every twelve months or more frequently, as clinically appropriate)
3. Diagnostic laboratory services

Medical criteria

Cervical cancer screening is covered when ordered and collected by a network provider under one of the following conditions:

1. The member has not had a screening Pap smear or other cervical cancer screening test during the preceding 12 months; or

2. There is evidence (on the basis of her medical history or other findings) that indicates the presence of cervical or vaginal cancer or other abnormalities; or that she is at high risk of developing cervical or vaginal cancer. The high risk factors for cervical and vaginal cancer are:
 - a.) Cervical Cancer High Risk Factors:
 - Early onset of sexual activity (under 16 years of age);
 - Multiple sexual partners (five or more in a lifetime);
 - History of a sexually transmitted disease (including HIV infection); and
 - Fewer than three negative Pap smears within the previous 7 years.
 - b.) Vaginal Cancer High Risk Factors:
 - DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy.
3. Surveillance Pap smear(s) medically necessary to monitor a patient's medical condition as clinically appropriate as determined by the attending physician.

Exclusions

1. Services that do not meet the above criteria.
2. Routine cervical cancer screening within 12 months of a previous Pap smear unless medically necessary.
3. Computerized screening or rescreening techniques (e.g., AutoPAP[®] or PAPNET[®]).
4. Office visits, procedures or other services provided by a non-network provider.

Copayment

All services subject to copayments, deductible and coinsurance amounts defined in the *Member Handbook/Evidence of Coverage*.

References

1. Brown A, Garber, AM. Cost-effectiveness of 3 Methods to Enhance the Sensitivity of Papanicolaou Testing. *JAMA* 1999;281:347-353.
2. Nanda K and others. Accuracy of the Papanicolaou Test in Screening for and Follow-up of Cervical Cytologic Abnormalities: A Systemic Review. *Ann Intern Med.* 2000;132:810-819.
3. Ashfaq R, Gibbons D, Vela C, Saboorian MH, Illiya F. ThinPrep Pap Test: Accuracy for Glandular Disease. *Acta Cytol* 1999;43:81-85.
4. O'Leary TJ, Tellado M, Buckner SB, Ali IS, Stevens A, Ollayos CW. PAPNET-assisted rescreening of cervical smears: cost and accuracy compared with a 100% manual rescreening strategy. *JAMA* 1998 Jan 21;279(3):235-7.
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6. Cox TJ. Evaluating the Role of HPV Testing for Women With Equivocal Papanicolaou Test Findings. *JAMA* 1999 May 5;281(17):1645-1647.
7. Sedlacek TV and others. Cost-effectiveness of Methods to Enhance Sensitivity of Papanicolaou Testing. *JAMA* 1999 Oct 20; 282(15):1419-1420.
8. Koss LG and others. Human Papillomavirus Testing as a Screening Tool for Cervical Cancer. *JAMA* 2000 May 17;283(19):2525-2527.
9. Minge L, Fleming M, VanGeem T, Bishop J. AutoCyte Prepâ System vs. Conventional Cervical Cytology Comparison Based on 2,156 Cases. *J Reprod Med* 2000;45:179-184.
10. Vassilakos P, et al. Biopsy-Based Comparison of Liquid-Based, Thin-Layer Preparations to Conventional Pap Smears. *J Reprod Med.* 2000;45:11-16.
11. Bishop J, Chevront D, Sims K. Evaluation of the AutoCyte Screen System in a Clinical Cytopathology Laboratory. *Acta Cytol* 2000;44:128-136.
12. Hayes Medical Technology Assessment Reports –
 - ThinPrep Pap Smear Test for Detecting Cervical Cancer (THIN0403.08, Rev. 05/98)
 - Computer-Assisted Rescreening of Pap Smears (COMP0403.20, Rev. 05/98)

13. Agency for Health Care Policy and Research -
 - Evaluation of Cervical Cytology. Summary, Evidence Report/Technology Assessment: Number 5, January 1999. Agency for Health Care Policy and Research, Rockville, MD
<http://www.ahrp.gov/clinic/cervsumm.htm>.
14. Institute for Clinical Systems Improvement (ICSI): Healthcare Guidelines
 - Management of Initial Abnormal Pap Smear. May 1999.
 - Cervical Cancer Screening. January 2000.
15. Massachusetts Health Quality Partners (MHQP) Preventive Health Care Guidelines 2003
16. Massachusetts General Law - Chapter 175: Section 47G. Cytologic screening and mammographic examination expense benefits.
17. Medicare National/Local Policy:
 - MED-MANUAL, MED-GUIDE ¶10,206.01, Screening Pap Smears and Screening Pelvic Exams [Medicare Intermediary Man., §3628.1], as revised by Trans. No. 1773, April 1999
 - MED-MANUAL, MED-GUIDE ¶27,201, Coverage Issue Manual §50-20.1 Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer (Revised by Transmittal No. 103, effective January 1, 1998).
 - PROG-MEM, MED-GUIDE 2000-1 MED-GUIDE-TB ¶150,926, Cervical and Vaginal Diagnostic Tests in Calendar Year 2000., Program Memorandum (Intermediaries/Carriers Manual), HCFA Pub. 60AB , (Dec. 01, 1999)
18. New Devices Aim at Improving Pap Test Accuracy, FDA Consumer October 1996.
19. FDA Talk Paper (T98-23, 05/05/98) FDA Approves First Automated System for Primary Screening of Pap Smears.
20. FDA Talk Paper (T95-55, 10/03/95) FDA Approves New Pap Smear Screening System.
21. ACOG News Release:
 - ACOG Says New Pap Technologies Not Standard of Care. July 31, 1998.
 - Critical Commentary: Invest in Health Resources in Widespread Pap Screening, Not New Technologies. July 31, 1999.
22. ACOG Committee on Gynecologic Practice:
 - Committee Opinion, New Pap Test Screening Techniques. Number 206, August 1998.
 - Primary and Preventive Care: Periodic Assessments. Number 229, December 1999.
 - Routine Cancer Screening. Number 185, September 1997.
 - Recommendations on Frequency of Pap Test Screening. Number 152, March 1996.
 - ACOG Technical Bulletin/Cervical Cytology: Evaluation and Management of Abnormalities. Number 183, August 1993.
23. Cytoc Corporation Marketing Information:
 - Answers to Frequently Asked Questions about the ThinPrep System.
 - Why you should be using the ThinPrep Pap Test.
 - The ThinPrep System – How It Works.
 - The Advantages of the ThinPrep Pap test are Clear.
 - Summary of Clinical Data.
 - Gynecological Case Presentation – May 2000
24. TriPath Marketing Information:
 - Our Products – AutoCyte PREP System.
 - PREP System.
 - Instructions for Use – Liquid-Based Monolayer Pap Preparations.
25. This policy has been reviewed and endorsed by Plan affiliated and non-affiliated specialty care physicians.

Products to which this policy applies

- FCHP Direct, FCHP Select Care (HMO)
- FCHP Flex Care Direct, FCHP Flex Care Select (Dual Certificate)
- Fallon Preferred Care (PPO)
- FCHP MassHealth
- Non-group: FCHP Independent Care, Direct Enrollment, Bill-at-Home

Medicare

Mandated benefit/regulatory issues

- Federal
- Commonwealth of Massachusetts
- Medicare – National Policy
- Medicare – Local Medical Review Policy
- Not applicable

Policy/Committee review

Technology Assessment Committee – 08/00, 10/00, 12/00, 10/04/05

Benefits Committee – 02/01

Utilization Management Committee – 06/03

Technology Assessment Subcommittee – 05/24/05

Approved by: *Signature on file*
Dennis A. Batey, MD – Chief Medical Officer

Date: 10/04/05