

UPMC Health Plan POLICY AND PROCEDURE MANUAL

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SUBJECT: Human Papilloma Virus Testing
INDEX TITLE: Medical Management
ORIGINAL DATE: November 2006

This policy applies to the following lines of business: (Check those that apply.)

COMMERCIAL:					
HMO ()	POS ()	PPO ()	OOA ()		
Fully Insured ()	Self-funded/ASO ()	HSA ()	All (X)		
Medicare Select ()	Medicare Supplement ()	Individual Product ()			
DPW-MA:					
Health Choices ()	Voluntary ()			All (X)	
CMS-MA:					
OH ()	WV ()	PA ()	All (X)	Other ()	
HMO (X)	PPO (X)	Specialty Needs Plan (X)	Part D ()	PFFS (X)	All ()
PID-CHIP/AdultBasic:					
Free () CHIP only	Sub/CHIP ()	Sub/AB ()	Full/CHIP ()	Full/AB ()	All/CHIP () All/AB (X)
ANCILLARY:					
Dental ()	Vision ()				
APPLICABLE TO:					
Community Care ()	Work Partners ()				

I. POLICY

It is the policy of UPMC Health Plan to recognize the value of new technology in the diagnosis and management of disorders associated with Genotype testing. Information derived from this type of DNA analysis answers many questions which often cannot be answered by conventional pathology evaluation.

Cervical cancer screening by testing for the Human Papilloma Virus (HPV) is recognized as truly differentiating abnormal cytology results from normal results, thus helping to focus on members who are at risk and in need of further management. This screening is also based on the member's individual benefit plan.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the appropriate indications for HPV testing.

IV. SCOPE

This policy applies to various UPMC Health Plan departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to: Medical Management, Benefit Configuration, Claims and Quality Audit Departments.

V. PROCEDURE

A. Medical Description/Background

Traditional Pap tests have helped physicians detect abnormal cells before they become cancerous, but the technique is not perfect. The Pap test sometimes detects atypical squamous cells of undetermined significance (ASC-US) or low-grade squamous intraepithelial lesions (LSIL) - mild abnormalities that are usually transient but could signal precancerous cells. Without the ability to identify the small proportion of lesions that will become cancerous, these results can lead to unnecessary patient anxiety, further diagnostic procedures (e.g. colposcopy), and treatment.

HPV has been associated with the development of cervical intraepithelial neoplasia (CIN) that can then progress to invasive cervical cancer. About 30 of the 70 different genotypes of HPV have thus far been identified to infect the cervix. Researchers have been able to classify each of these 30 genotypes into low, intermediate, and high-risk categories, based on the risk for progression to cervical cancer. HPV is present in about 81% of patients with cervical neoplasia and in almost 100% of patients with cervical cancer. However, studies have also shown that 90% of younger women who test positive for HPV tend to resolve within 2 years with no progression to cancer.

Studies show that abnormal pap tests which are also HPV positive are more likely to be associated with abnormal colposcopic exams than abnormal pap tests that are HPV negative. Women with normal Pap tests results and no HPV infection are at a very low risk for developing cervical cancer.

HPV testing is not intended to substitute for regular routine pap tests (cytology) screening for cervical cancer. Nor is it intended to screen for women under 30 who have normal pap tests. Although the rate of HPV infection in this sexually active younger age group is high, most infections are short-lived and resolve in a couple of years, and have not been shown to be associated with cervical cancer.

B. Indications

1. HPV DNA testing is considered medically necessary for assessment of women 21 years of age and older with atypical squamous cells of undetermined significance (ASC-US). **If HPV test is positive** – recommend colposcopy. **If HPV test is negative** – re-screen with Pap in 1 year as a second HPV test is not medically necessary in these cases.

2. The use of a combination Pap test and HPV screening is considered medically necessary for screening women aged 30 years and older.
 - **If both tests are negative**, then rescreening with HPV and Pap test should only be done in 3 years. Automatic rescreening with HPV and Pap test in 1 year is not medically necessary. Rescreening with HPV before 3 years will not be covered
 - **If the Pap test is negative and HPV test is positive**, then rescreen the member with Pap and HPV tests in 1 year.
 - **If subsequent Pap and HPV are both negative**, rescreen at 3 years.
 - **If subsequent Pap is ASCUS and HPV is negative, then rescreen with Pap and HPV in 1 year.**
 - **If subsequent Pap is greater than ASCUS and HPV is negative, proceed to colposcopy.**
 - **If any Pap result and HPV are positive, proceed to colposcopy.**
Note: If PAP is negative and High risk HPV is positive, then you have the option of genotyping for HPV 16 & 18 without waiting for a year and if either one of them is positive, you may proceed to colposcopy.
3. Women 21 years of age and older diagnosed with CIN 1 preceded by ASCUS, ASC-H (atypical squamous cells: can't exclude high-grade) or LSIL may be managed with either HPV testing at 12 months **OR Pap tests** at 6 and 12 months.
 - **If there is one negative HPV test at 12 months or two negative Pap tests**, then return to routine follow-up.
 - **If follow-up HPV testing is positive** or follow-up cytology at 6 or 12 months is greater than or equal to ASCUS, then colposcopy is recommended.
4. HPV testing at 6-12 months can be used in the post treatment management of women 21 years and older who have been diagnosed with CIN 2/3.
 - If HPV testing is negative, the patient should return to annual screening.
 - If HPV testing is positive, the patient should undergo a colposcopy.
5. In women 21 years and older with atypical endocervical, endometrial, or glandular cells NOS, HPV DNA testing is preferred at the time of colposcopy (if not already performed).

C. Limitations

HPV testing is not indicated:

- In adolescents (20 years of age and younger) due to the high rate of spontaneous clearing of HPV infection in this age group
- Testing is not of value post hysterectomy for a benign condition

D. Variations

N/A

E. Quality Audit

Quality Audit may monitor policy compliance or billing accuracy at the request of the UPMC Health Plan's Technology Assessment Committee or the Benefits Reimbursement Committee.

F. Records Retention

Records Retention for UPMC Health Plan documents, regardless of medium are provided within the UPMC Health System Policy and as indicated in the UPMC Insurance Services Division Policy and Procedure.

G. References

1. Cox JT, Lorincz AT, Schiffman MH, Sherman ME, Cullen A, Kurman RJ. Human papillomavirus testing by hybrid capture appears to be useful in triaging women with a cytologic diagnosis of atypical squamous cells of undetermined significance. *Am J Obstet Gynecol* 1995 Mar; 172(3): 946-54.
2. Ferris DG, Wright TC Jr, Litaker MS, Richart RM, Lorincz AT, Sun XW, Borgatta L, Buck H, Kramer L, Rubin R. Triage of women with ASCUS and LSIL on Pap tests reports: management by repeat Pap tests, HPV DNA testing or colposcopy? *J Fam Pract* 1998 Feb; 46(2):125-34.
3. Manos MM, Kinney WK, Hurley LB, Sherman ME, Shieh-Ngai J, Kurman RJ, Ransley JE, Fetterman BJ, Hartinger JS, McIntosh KM, Pawlick GF, Hiatt RA. Identifying women with cervical neoplasia: using human papillomavirus DNA testing for equivocal papanicolaou results. *JAMA* 1999 May 5; 281(17):1605-10.
4. Vassilakos P, Demarval F, Munoz M, Broquet G, Campana A. Human papillomavirus (HPV) DNA assay as an adjunct to liquid-based pap test in the diagnostic triage of women with an abnormal pap tests. *Int J Gynecol Obstet* 1998 Apr; 61(1):45-50.
5. Factsheet for SB1245 (HPV Screening & Cervical Cancer) – 3/17/06 Senator Figueroa bill to Senate democratic caucus – to be reviewed April 19, 2006.
6. Kulasingam, S. L., J. P. Hughes, N. B. Kiviat, *et al.* (2002). "Evaluation of human papillomavirus testing in primary screening for cervical abnormalities: comparison of sensitivity, specificity, and frequency of referral." *Jama* 288(14): 1749-57.
7. Moscicki, A. B., S. Shiboski, J. Broering, *et al.* (1998). "The natural history of human papillomavirus infection as measured by repeated DNA testing in adolescent and young women." *J Pediatr* 132(2):277-84.
8. Munoz, N., F. X. Bosch, S. de Sanjose, *et al.* (2003). "Epidemiologic classification of human papillomavirus types associated with cervical cancer." *N Engl J Med* 348(6): 518-27.

9. Ratnam, S., E. L. Franco and A. Ferenczy (2000). "Human papillomavirus testing for primary screening of cervical cancer precursors." *Cancer Epidemiol Biomarkers Prev* 9(9): 945-51.
10. Sherman, M. E., A. T. Lorincz, D. R. Scott, *et al.* (2003). "Baseline cytology, human papillomavirus testing, and risk for cervical neoplasia: a 10-year cohort analysis." *J Natl Cancer Inst* 95(1): 46-52.
11. Solomon, D., M. Schiffman and R. Tarone (2001). "Comparison of three management strategies for patients with atypical squamous cells of undetermined significance: baseline results from a randomized trial." *J Natl Cancer Inst* 93(4): 293-9.
12. Womack, S. D., Z. M. Chirenje, P. D. Blumenthal, *et al.* (2000a). "Evaluation of a human papillomavirus assay in cervical screening in Zimbabwe." *Bjog* 107(1): 33-8.
13. Darragh TM and TJ Colgan "ASCCP '06 Consensus Guidelines – What's New and Different?" PAP/NGC program Reviews, November 2007.
Online:http://www.cap.org/apps/cap.portal?nfpb=true&cntvwrPtl.actionOverride=%2Fportlets%2FcontentViewer%2Fshow&_windowLabel=cntvwrPtl&cntywrPtl%7BactionForm.contentReference%7D=cap_today%2Fpap_ngc%2F1107NGC_Main.html&_state=maximized_pageLabel=cntvwr
14. Davey DD *et al.* "Bethesda 2001. Implementation and reporting rates: 2003 Practices of Participants in the College of American Pathologists Interlaboratory Comparison Program in Cervicovaginal Cytology" *Archives of Pathology & Laboratory Medicine*. 2004;128:1224-1229.
15. Davis AJ. "Cervical Cancer: Mew Guidelines for Screening and Prevention". *Journal Watch Women's Health*. 2007, November 29.
16. Massad LS *et al.* "Biopsy Correlates of Abnormal Cervical Cytology Classified Using the Bethesda System". *Gynecologic Oncology*. 2001;82:516-522.
17. Melnikov J, *et al.* "Natural History of Cervical Squamous Intraepithelial Lesions: A Meta-analysis" *Obstetrics and Gynecology* 1998; 92 (4 pt 2):727-735.
18. Moscicki AB *et al.* "Regression of Low Grade Squamous Intraepithelial Lesions in Young Women" *Lancet* 2004; 364: 1678-1683.
19. Nobbenhuis MA *et al.* "Cytological Regression and Clearance of High-Risk Human Papillomavirus in Women with an Abnormal Cervical Tests. *Lancet*: 2001, 358:1782-1783.
20. Numnum TM *et al.* "A Prospective Evaluation of "See and Treat" in Women with H SIL Pap Tests Results: Is this an Appropriate Strategy?" *Journal of Lower Genital Tract Disease*. 2005;9:206.
21. Sadler L and Saftlas A: "Cervical Surgery and Preterm Birth" *Journal of Perinatal Medicine*. 2007;35:5 – 9.
22. Schlecht NV *et al.* "Human Papillomavirus Infection and Time to Progression and Regression to Cervical Intraepithelial Neoplasia". *Journal of the National Cancer Institute*. 2003; 95:1336-1343.
23. Stoler, MH and Schiffman, M: "Interobserver Reproducibility of Cervical Cytologic and Histologic Interpretation: Realistic Estimates from the ASCUS-LSIL. Triage Study". *JAMA* 2001;285:1500-1505.
24. Wright, TC *et al.* "2006 Consensus Guidelines for the Management of Women with Cervical Intraepithelial Neoplasia of Adenocarcinoma in Situ" *Journal of Lower Genital Tract Disease*. 2007, November 4:11:223-239. American College of

Obstetricians and Gynecologists (ACOG). New pap test screening techniques. Washington (DC): American College of Obstetricians and Gynecologists; 1998 Aug. (ACOG Committee Opinions; no. AC206).

25. American Cancer Society Guidelines for early detection of cervical neoplasia and cancer-major recommendations and when to discontinue screening.- August 2003
26. Brigham & Women's Hospital: Cancer screening recommendation- 2004 Dec.29.US Preventive services Task Force(USPSTF) – Screening for Cervical Cancer Jan.2003
27. FDA, Cervista™ HPV HR and HPV 16/18, 03/2009

Disclaimer:

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