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Comments and Responses Regarding Draft Local Coverage Determination: Human Papillomavirus (HPV) Testing

As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Human Papillomavirus (HPV) Testing LCD. The official notice period for the final LCD begins on April 15, 2009, and the final determination will become effective on July 1, 2009.

Comment: A commenter noted that HPV testing is used to test head and neck cancers. The *in situ* technique was primarily used but he was concerned the probe technique might be used in some instances.

Response: At present, tumor HPV status does not affect treatment decisions, and thus such testing is not medically necessary.^{1,2}

Comment: A commenter stated that a PAP smear with HPV testing is not a required standard of care, but it is acceptable and appropriate as per the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin #61, April 2005.

¹ Fakhry C, Westra WH, Li S, et al. Improved survival of patients with human papillomavirus-positive head and neck squamous cell carcinoma in a prospective clinical trial. *J Natl Cancer Inst.* 2008;100:261-269.

² Chustecka Z. HPV-positive head and neck cancer has better response to treatment. Available at: http://www.medscape.com/viewarticle/570211_print. Accessed 03/10/2009.

"Use of a combination of cervical cytology and HPV DNA screening is appropriate for women aged 30 years and older. If this combination is used, women who receive negative results on both tests should be rescreened no more frequently than every 3 years."

Response: The only screening test presently approved for Medicare beneficiaries is cervical cytology, i.e., a PAP smear. Screening tests are covered under Medicare only when specifically delineated in the Social Security Act. Expanding the screening benefit for cervical cancer is not within the purview of NGS.

Comment: A commenter strongly suggested that HPV testing be covered every three years. In some women, sampling is an issue and high-grade disease is missed by a PAP smear but not by HPV testing on follow up.

Response: Please see the prior response.

Comment: A commenter suggested that HPV testing be covered when testing a woman whose partner is positive for HPV.

Response: Without signs or symptoms of infection, testing for HPV would be screening. As noted above, NGS can not expand the scope of cervical cancer screening.

Comment: A commenter suggested that a diagnosis of an atrophic cervix and an unsatisfactory PAP smear should be added as an indication for the test.

Response: An atrophic cervix is not an indication for HPV testing. Because cervical cancer screening in Medicare is limited to cervical cytology (PAP), NGS can not allow for HPV testing due to an unsatisfactory PAP.

Comment: A commenter asked that a previous history of HPV be added as an indication.

Response: As noted in the 2006 consensus guidelines for the management of women with abnormal cervical cancer screening tests, "...the vast majority of HPV infections spontaneously clear within 2 years after infection and are of little long-term significance." Thus a history of HPV infection is not an indication for HPV testing.

Comment: A commenter requested the following changes:

- HPV testing should not take place in adolescent women as a triage test;

- If a woman with ASC-H (atypical squamous cell, cannot rule out high grade lesion) has a colposcopy and biopsy and displays no evidence of CIN 2 or 3 (high grade dysplasia), then HPV testing should be done every 12 months with repeat colposcopy and biopsy if it is positive despite a negative Pap smear.

Response: We agree that HPV testing has no place in adolescent women. As noted, the indication for ASC-H has been added to the LCD.

Comment: A commenter requested coverage for HPV testing after a cervical cytology result of “atypical glandular cells of uncertain significance (AGC / AGUS).”

Response: This indication has been added to the LCD.