March 24, 2017

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Re: Draft Local Coverage Determination – Infectious Disease Molecular Diagnostic Testing (DL37007)

Dear Dr. Awodele:

On behalf of the College of American Pathologists (CAP) and the Association for Molecular Pathology (AMP), thank you for the opportunity to comment on DL37007. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the College of American Pathologists (CAP) serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

The AMP is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics.

Following are our concerns and recommendations relating to this draft policy for your consideration.

Documentation Requirements (page 3):

dLCD statement: "When using non-FDA-approved tests, the laboratory should maintain in the patient's medical record the information substantiating the medical necessity of the test and should make that information available to Medicare upon request".

Comment: Laboratories do not keep patient medical records nor do they always have access to them. The treating physician, and not the laboratory, must take responsibility for the medical necessity of the test because only the treating physician, not the laboratory, will have the necessary information to make that determination. For this reason we feel it would not be reasonable to hold the laboratory responsible for substantiating the medical necessity of any test, whether FDA-approved or otherwise; this is especially pertinent as there are many tests for which there is no FDA-approved alternative and, under CLIA, it is the laboratory's responsibility to be able to document the validity of the test for the analyte it purports to assay.

Recommend: That the draft policy statement mentioned above be omitted from the policy for the aforementioned reasons.

Group 10 Codes (page 20):

Comment: The dLCD does not appear to allow for initial screening of women with both an HPV test and a Pap test ("co-testing"). What is described appears to be HPV testing alone as a follow-up in women with a history of HSIL (dysplasia, CIN2-3 or worse), and reflex of AGC, ASC-US and LSIL from a Pap test.

In 2011, the American Cancer Society, the American Society for Colposcopy and Cervical Pathology, and the American Society for Clinical Pathology updated screening guidelines for early detection of cervical cancer and precursors to cervical cancer. These experts recommended the screening strategies of cytology and co-testing[1].

Recommend: That the policy include HPV testing in conjunction with a Pap test in women 30 years and older as a cervical cancer screening ("co-testing"), and that the following related codes be added: 795.02, 795.04, 795.06-795.10, v10.40-v10.44, v15.89, v69.2, v72.31, v72.32, v73.81, v76.2, v76.47, v76.49, and v95.01. We also recommend that the policy include the option to use HPV testing as a primary screening test.

Additional Comments and Recommendations:

Comment: The Cancer Care Ontario guidelines[2,3] as well as the general consensus among CAP experts, suggests that testing for HR-HPV be done routinely for the following situations:

- Tumors of all adults presenting with oropharyngeal SCC
- Neck nodal tissue from all patients with metastatic SCC of unknown primary

With regard to testing, most would agree that IHC for p16 is a high sensitivity test, though not entirely specific, and that other tests that may appropriately be used in combination with p16 (or possibly alone), including in situ hybridization for DNA or RNA, and PCR for HPV DNA.

Recommend: The policy be revised to include routine testing for HR-HPV tumors of all adults presenting with oropharyngeal SCC and neck nodal tissue from all patients with metastatic SCC of unknown primary.

Comment: NCCN guidelines state "either immunohistochemistry for analysis of p16 expression or HPV in situ hybridization for detection of HPV DNA in tumor cell nuclei is recommended." The guidelines encourage HPV testing in patients with head and neck cancer because of its prognostic value[4].

Recommend: The policy be revised to include routine testing for HPV to assess prognosis of head and neck cancer in patients and that the following ICD-9 codes should be added 141.0-141.9, 145.0-145.9, and 146.0- 146.9.

We respectfully ask that you consider these comments which were prepared by members of CAP and AMP pathologists who provide services to Medicare beneficiaries covered by CGS. We are happy to be of assistance in providing additional clinical information, references, contacts, or whatever is needed to assist you with this dLCD. Please direct your correspondence to Nonda Wilson, CAP Manager, Economic and Regulatory Affairs, at nwilson@cap.org or to Mary Steele Williams, AMP Executive Director, at mwilliams@amp.org

References

1. Huh WK, Ault KA, Chelmow D, et al. Use of primary high-risk human papillomavirus testing for cervical cancer screening: interim clinical guidance. Gynecol Oncol. 2015; 136(2):178-182.

2. Cancer Care Ontario guidelines (Routine HPV Testing in Head and Neck Squamous Cell Carcinoma) Lacchetti, C, Waldron J, Perez-Ordonez, B, Kamel-Reid S, Cripps C, Gilbert R. Routine HPV Testing in Head and Neck Squamous Cell Carcinoma. Toronto (ON): Cancer Care Ontario; 2013 May 13. Program in Evidence-based Care Evidence-based Series No.: 5-9.

3. Cancer Care Ontario Cervical Screening guidelines Murphy J, Kennedy E, Dunn S, Fung Kee Fung M, Gzik D, McLachlin CM, et al. Cervical Screening. Toronto (ON): Cancer Care Ontario; 2011 Oct 5. Program in Evidence-based Care Evidence-based Series No.: 15-9.

4. National Comprehensive Cancer Network. Head and Neck Cancers (Version 1. 2017) http://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed March 17, 2017.