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RE: Draft Local Coverage Determination – BRCA 1 and BRCA 2 Genetic Testing (DL36161, DL36163)

Dear Dr. Lurvey:

Thank you for the opportunity to comment on DL36131 and DL36163. AMP (Association for Molecular Pathology) 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. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

The College of American Pathologists (CAP) is a national medical specialty society representing more than 17,000 physicians who practice anatomic and/or clinical pathology. College members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities.

Members of both AMP and CAP are experts in molecular pathology and the implementation of this coverage policy will directly impact their practices. We are submitting joint comments because at this time both of our organizations share the same concerns regarding this draft LCD, and, as such, we request that Noridian consider the joint recommendations outlined in this letter.

First, we thank you for your decision to cover BRCA1 and BRCA2 testing under many circumstances. In particular, we agree that a personal history of female breast cancer should certainly be a clinical indication for testing, although (as discussed below), we request a clarification of policy regarding those patients who have been adopted, or for whom there is no available family history. Additionally, we believe that certain other critical indications have been overlooked in this LCD, as described below, and that the LCD should be appropriately revised to incorporate these changes.

1. Clarify Indicators for Individuals who have Been Adopted

In situations where patients with a personal history of breast or another BRCA-related malignancy have been adopted or do not otherwise have access to accurate family health information, we recommend clarification on coverage for BRCA1 and BRCA2 testing. These individuals should be covered for this testing in most circumstances.

2. Personal History for Other Cancers

AMP and CAP commend Noridian for recognizing that BRCA1 and BRCA2 should be performed in high-risk patients with cancers other than female breast cancer. However, to better match gold standard NCCN inherited cancer genetic testing guidelines, which appear to be the appropriate reference source for Noridian's coverage criteria details in this particular policy document, the third bullet point of section 2 (Personal History of Other Cancer) needs to be revised to include those patients with a personal history of pancreatic or prostate cancer with ONE or more (not two or more) close blood relatives with a BRCA-related cancer.

Furthermore, NCCN guidelines specifically recommend BRCA testing for all pancreatic cancer patients of Ashkenazi Jewish ancestry, regardless of family history. Noridian's requirement for a documented family history in these Ashkenazi Jewish pancreatic cancer patients should thus be eliminated. Founder mutations similar to the three identified in the Ashkenazi Jewish population have also been identified in other cultural and geographic populations (Fackenthal JD and Olopade OI, 2007). Similarly burdened families should thus also qualify for coverage. BRCA1 and BRCA2 genes were identified through the screening of individuals, affected and unaffected, in burdened families among varied cohorts.

3. Eliminate the "Once in a Lifetime" Testing Requirement

Though we agree that *under most circumstances*, BRCA1 and BRCA2 testing need only be conducted once in a patient's lifetime, as technology continues to advance rapidly, actionable mutations that could be missed with current testing methods may not be missed in the future. We request the opportunity, in some limited scenarios, to test patients more than once per lifetime as the technology advances to improve testing sensitivity.

4. Multigene Panels

We commend Noridian for providing coverage for BRCA1 and BRCA2 testing when it is included in a multigene panel. However, as Noridian currently does not reimburse for any of the CPT codes specifying these multigene panels, it is unclear how this testing would be paid.

RECOMMENDATION:

If BRCA1 and BRCA2 testing is to be covered when performed as part of these multi-gene panels, we specifically recommend that CPT codes 81445 and 81455 should be added to this coverage policy.

We also recommend that CPT 81213 (uncommon dup/del variants) should be added to this coverage policy to allow appropriate (lower cost) payment for those individuals/families with founder mutations who are of ancestry other than Ashkenazi Jewish (Fackenthal and Olopade, 2007).

5. Coverage for Additional ICD-10 and CPT Codes

We believe that the list of covered ICD-10 codes is nearly complete as proposed, but recommend that Noridian add the following ICD-10 codes to the policy:

C50.211 Malignant neoplasm of upper-inner quadrant of right female breast
C50.212 Malignant neoplasm of upper-inner quadrant of left female breast
C50.219 Malignant neoplasm of upper-inner quadrant of unspecified female breast

6. The Technical Assessment Requirement Fails to Meet the LCD Requirement

We disagree with the MolDx program requirement that all BRCA1 and BRCA 2 laboratory tests undergo a Technical Assessment to be eligible for reimbursement under this coverage policy. The TA process lacks the transparency that the LCD process requires for creating local coverage policy. To ensure that LCDs that affect Medicare beneficiaries would not be based solely on the internal review by the MAC, CMS created the LCD process to require public participation in the LCD process in a manner similar to the process used at the national level. PIM 83 Chapter 13 provides specific instructions that require the draft LCD be presented to and involve the medical community and affected public in review and comment, beginning with a public meeting in some cases, presentation to the CAC and a formal Comment and Notice process.

The TA process involves only Noridian and the requesting lab. The requesting lab submits its documents for the TA process through the McKesson online tool. The developer/laboratory who has requested the TA is able to comment on the TA report before it is finalized. The public cannot access information on the McKesson site about the evidence documents submitted by the requesting lab or the evidence reviewed. The documents submitted for the Technical Assessment are not publicly available or cited in the final decision

The TA process uses Subject Matter Experts (SME) who are known only to Noridian, with unknown expertise for the condition, gene/analyte and use under review. The SME review material provided by the requesting laboratory is known only to Noridian, with recommendations made by the SME also known only to Noridian. Based on how it functions and what is presented publicly by Noridian, the TA process used by the MolDX Program to assist it in making coverage decision is an internal review process. There is no public component for the medical community, other laboratories, or patients who will be impacted by the decisions. As Chapter 13 states: “Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community.” [PIM 83 §13.7.1 Evidence Supporting LCD]. We believe this statement applies to recommendations made by an internal review process.

It is worthy of note that Congress saw fit in the recent *Protecting Access to Medicare Act of 2013* to mandate adherence to the Medicare process in making local coverage determinations, and adoption by the MolDx program of the TA requirement fails to comply with this mandate. Therefore, we request that the TA requirement be eliminated.

We respectfully ask that you consider these comments which were prepared by a consortium of providers in the Noridian jurisdiction as well as other members of the Association for Molecular Pathology, College of American Pathologists, laboratory directors, staff and consultants who provide service to Medicare beneficiaries covered by Noridian. We are happy to be of assistance in providing additional clinical information, references, contacts, or whatever is needed to assist you with this draft LCD. Please direct your correspondence to Mary Steele Williams, AMP Executive

Director, at mwilliams@amp.org or Nonda Wilson, CAP's Manager, Economic and Regulatory Affairs, at nwilson@amp.org.

Sincerely,

Association for Molecular Pathology
College of American Pathologists

References:

Lynch HT, Deters CA, Snyder CL, Lynch JF, Villeneuve P, Silberstein J, Martin H, Narod SA, Brand RE. BRCA1 And pancreatic cancer: pedigree findings and their causal relationships. Cancer Genet Cytogenet 2005 158(2): 119-25.

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