



July 7, 2016

Novitas Solutions Medical Policy Department
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RE: Draft Local Coverage Determination – BRCA 1 and BRCA 2 Genetic Testing (DL36715)

Dear Dr. Patterson,

Thank you for the opportunity to comment on DL36715. The Association for Molecular Pathology (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. 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 18,000 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 Novitas 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.

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.

2. Eliminate the “Once in a Lifetime” Testing Requirement

With regard to “genetic testing,” there is an important distinction between inherited and acquired conditions: while a specific molecular diagnostic test for an inherited condition would typically be indicated only once in a lifetime for a beneficiary, more frequent molecular testing may be medically reasonable and necessary in acquired conditions such as malignancies, including separate malignancies developing at different times and/or locations, and recurrent malignancies as they are treated and followed, in order to assess response or

other relevant clinical criteria. A not uncommon scenario would be a woman with a family and personal history of breast cancer who initially tests negative for a germline BRCA1/2 mutation (when she is first diagnosed with breast cancer) and then, years later, develops a (perhaps secondary?) ovarian cancer with an acquired somatic cancer cell-specific BRCA1/2 mutation that would render the tumor susceptible to PARP inhibitor therapy. Without BRCA re-testing of the tumor tissue (not germline), this patient would be denied effective therapy.

On this basis, we recommend rather than an absolute prohibition on retesting, that there be an acknowledgement that any such repeat testing would be on the basis of individual consideration.

3. Coverage for Additional ICD-10 Code

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

C50.219 Malignant neoplasm of upper-inner quadrant of unspecified female breast

We respectfully ask that you consider these comments which were prepared by a consortium of providers in the Novitas 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 Novitas. 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 Tara Burke, AMP Policy Analyst, at tburke@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