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Submitted electronically to: J11B.Policy@PalmettoGBA.com

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RE:
Proposed LCD ID - DL36082
Proposed LCD Title - MolDX: BRCA1 and BRCA2 Genetic Testing

To Whom It May Concern:

Facing Our Risk of Cancer Empowered (FORCE) is pleased to submit the following comments regarding the proposed LCD “MolDX: BRCA1 and BRCA2 Genetic Testing.” FORCE is the only national nonprofit organization representing people and families affected by hereditary breast and ovarian cancer. FORCE programs provide education, support, advocacy and research to empower those affected by hereditary cancer to make informed decisions about their health, including decisions surrounding genetic counseling and testing.

We applaud the proposed LCD’s adoption of BRCA testing criteria for patients with breast, ovarian, and now pancreatic or prostate cancer based on the NCCN Clinical Practice Guidelines in Oncology: Genetics/Familial High-Risk Assessment: Breast and Ovarian, Version 1.2015. Alignment with current NCCN guidelines will ensure that Medicare beneficiaries receive genetic counseling and testing services consistent with the current standard of care. As more research is done on the impact of genetic factors on disease, it is important for Medicare to keep pace with these advancements and to ensure that Medicare recipients have access to potentially lifesaving services such as genetic testing for a strong predisposition to cancer.

**Nationally Covered Indications**

1. Personal History of Female Breast Cancer and 2. Personal History of Other Cancer

- We pleased to see that the proposed LCD language in these sections generally aligns with NCCN 2015 for adults affected with breast, ovarian, fallopian, primary peritoneal, pancreatic, or prostate cancer.

- **Pancreatic Cancer in individuals with Ashkenazi Jewish ancestry**
  The proposed language indicates that individuals of Ashkenazi Jewish descent with pancreatic cancer are covered with one or more additional affected relatives. Current NCCN
criteria do not require any additional relatives to be affected beyond the patient. Given that pancreatic cancer is rare, and that the prevalence of BRCA mutations in the Ashkenazi Jewish population is relatively high (about 1 in 40 individuals), we feel the LCD language should follow NCCN guidelines and that a pancreatic cancer diagnosis and Jewish ethnicity should be sufficient medical history for testing.

**Recommendation:**
Align the LCD with the current NCCN Clinical Practice Guidelines in regard to BRCA testing of those with a personal history of pancreatic cancer.

- **Testing for a Known Mutation in the Family**
  Language in “BRCA1 and BRCA2 Testing Overview” under the “Background” section, describes recommendations that individuals with a diagnosis of cancer are eligible to be tested for a deleterious BRCA mutation that has been identified in a blood relative:

  “Testing of unaffected individuals or family members is not a covered Medicare service. However, once a mutation is identified in the family, Medicare eligible relatives with signs and symptoms of breast cancer are typically tested for that specific mutation only.”

**Recommendation:**
Add an additional bullet to sections 1. and 2. under “Nationally Covered Indications” to clarify that genetic testing for a known mutation in the family is a covered service for individuals with signs and symptoms of breast cancer.

- **Genetic Counseling**
  The proposed LCD aptly indicates that pre- and post-test genetic counseling by a cancer genetics professional independent of a laboratory is a requirement for those undergoing multigene panel testing. Individuals undergoing testing for a specific mutation such as BRCA also benefit substantially from genetic counseling.

**Recommendations:**
Add a bullet with the following language to sections 1. and 2. under “Nationally Covered Indications”:

“Pretest genetic counseling by a cancer genetics professional independent of the laboratory has been performed and posttest genetic counseling by a cancer genetics professional independent of the laboratory is planned.”

Under “Coding Information,” add CPT code 96040 to the list of CPT/HCPCS Codes covered in this LCD to enable Certified Genetic Counselors to provide their expertise to the patients will benefit from their services.
3. Multigene Panels
The promise and utility of genetic testing lies in testing the right person for the right genetic mutation. As such, we are pleased that the proposed LCD includes coverage of panel testing if the “Individual also meets criteria for at least ONE other hereditary cancer syndrome for which NCCN guidelines provide clear testing criteria and management recommendations, including but not limited to Li Fraumeni Syndrome, Cowden Syndrome, or Lynch Syndrome.”

- Genetic Counseling
  We applaud the requirement of pre- and post-test genetic counseling by a cancer genetics professional independent of a laboratory. Counseling is critical in providing patients with evidence-based information, psycho-social support, and community resources—especially with the introduction of multigene panels. Unfortunately, Certified Genetic Counselors, the professionals most qualified to deliver these services, are not recognized Medicare providers. Currently, Medicare will only reimburse genetic counseling billed by a physician with CPT code 99211. Oncologists are often put in the position to “counsel” patients, but generally do not have the time to provide this service adequately.

**Recommendation:**
Under “Coding Information,” add CPT code 96040 to the list of CPT/HCPCS Codes covered in this LCD to enable Certified Genetic Counselors to provide their expertise to the patients who most need their services.

**Limitations**
The draft LCD states that “BRCA testing is limited to once-in-a-lifetime.” We agree that a person’s germline BRCA status doesn’t change during his or her lifetime. However, the genetic testing technology available does change and improve. Patients who received BRCA testing without full sequencing and duplication/deletion analysis, for instance, may benefit from more comprehensive genetic testing. If a patient tested negative for a mutation with a limited panel, it is reasonable to repeat testing with an expanded BRCA panel, or to conduct multigene panel testing in an effort to determine risk and eligibility for targeted treatments.

Additionally, BRCA testing as a companion diagnostic for targeted therapy such as Lynparza should not disqualify patients from receiving other genetic testing, such as multigene panel testing or additional diagnostic testing to determine eligibility for future personalized therapies which rely on different companion diagnostic tests. About 15% of women with ovarian cancer carry a BRCA mutation, for instance, but as many as 25% of those with ovarian cancer have a genetic predisposition to cancer. As such, additional genetic testing has the potential to provide valuable information for managing personal and family cancer risk.
Testing unaffected individuals with a family history of breast and ovarian cancer
The initial draft LCD extended coverage of BRCA testing to asymptomatic individuals who meet specific family cancer history criteria. This recommendation is consistent with the United States Preventive Services Task Force’s “B” rating for these services. Extending genetic testing services to this population would have aligned Medicare coverage of these services with those covered by Affordable Care Act compliant plans. It would also bring Medicare in line with the increasing focus on prevention rather than treatment of disease. FORCE and the extended hereditary cancer community was disappointed to see this language removed from the draft LCD and hopes to work with CMS to extend these potentially lifesaving services to anyone who needs them, including survivors and unaffected carriers, in the future.

At a time when our country is moving toward personalized and precision medicine, we should strive to ensure that individualized risk assessment and screening is available. This draft LCD is a step in the right direction and we applaud Palmetto’s efforts to align its Medicare services with the existing standard-of-care. Thank you for your consideration of our comments.