July 24, 2015

Elaine Jeter, MD
Part B, Medical Affairs
J11 Palmetto GBA
J1 MolDx Program
P.O. Box 100190Columbia, SC 29202-3190

RE: Proposed LCD # DL36082 – MolDx: BRCA1 and BRCA2 Genetic Testing

Dear Dr. Jeter:

I am writing on behalf of the Society of Gynecologic Oncology (SGO) and its 2,000 members, regarding Draft LCD# DL36082 – MolDx: BRCA1 and BRCA2 Genetic Testing. The SGO is the premier medical specialty society for physicians trained in the comprehensive management of gynecologic cancers in women. Our purpose is to improve the care of women with gynecologic cancers by encouraging research and disseminating knowledge, raising the standards of practice in the prevention and treatment of gynecologic malignancies and collaborating with other organizations interested in women's health care, oncology and related fields.

As medical professionals with a special interest and expertise in gynecologic cancers, we dedicate our work to helping women conquer the cancers unique to them. We uphold the highest standards of quality care, and through research, we are creating new and innovative ways to improve the treatment and care of patients. SGO members advocate and contribute to a comprehensive approach to screening, diagnosis and treatment; empowering women with the knowledge to provide answers, support and hope. With this in mind, the SGO has reviewed with great interest Palmetto GBA's Draft LCD # DL36082 and respectfully submits the following comments regarding the section entitled, "National Covered Indications."

Proposed Edits to National Covered Indications

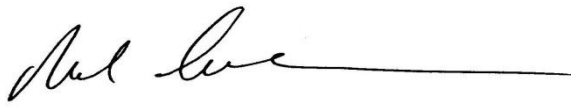
In general, the SGO urges Palmetto GBA to amend this Draft LCD to include national covered indications for those high risk individuals where *BRCA1 and BRCA2* genetic testing will impact the medical management of the individual being tested and/or their at-risk family members as articulated in the "Principles of Cancer Risk Assessments and Counseling Section of the Breast and Ovarian Cancer Genetic Assessment, NCCN Guidelines Version 2.2015, under the sub header, "Genetic Testing Consideration." In reviewing this Draft LCD # 36082 it appears that much of the content for the indications for coverage of genetic testing is taken from the NCCN guidelines. In particular, the recommendations for those individuals with a personal history of either female breast cancer or other cancer seem to be that which is stated in the NCCN algorithms. Therefore, the SGO urges Palmetto GBA to include the comprehensive NCCN guidelines on genetic testing, which would include those at high risk

of breast or ovarian cancer, in this draft LCD # DL 36082 prior to its finalization. Specifically, an individual from a family with a known deleterious *BRCA1/BRCA2* mutation should be included as an indication for Medicare coverage because information from a genetic test could impact the medical management of these individuals. SGO believes that indications for coverage of genetic testing should be expanded beyond just women with a personal history of cancer and should include Medicare beneficiaries without cancer who have a first-degree relative with a known mutation.

Finally, the SGO would urge Palmetto GBA to modify the paragraph in italics on page 4 of the Draft LCD # 36082 regarding NCCN guidelines recommending referral to various experts to actually reflect the medical professionals listed in that section of the NCCN guideline. The NCCN guideline states that oncologists, surgeons, oncology nurses and other healthcare professionals with expertise and experience in cancer genetics could also be providers of cancer risk assessment and genetic counseling.

SGO appreciates the opportunity to comment on this Draft LCD regarding *BRCA1* and *BRCA2* Genetic Testing. If we can provide additional information regarding this matter, please do not hesitate to contact Jill Rathbun, SGO Director of Government Relations at 703-486-4200.

Sincerely,



Robert Coleman, MD
President