Letter of Medical Necessity for BRCAvantage® Comprehensive

Physician Name, MD
Institution
Address
City, State and Zip Code

Date

Medical Director/Physician Name, MD
Insurance Company Name
Address
City, State and Zip Code

Re: Patient Name DOB: MM/DD/YYYY

Member ID: Group ID:

Dear Medical Director:

I am writing this letter on behalf of the above-referenced patient to request coverage for the BRCAvantage® Comprehensive test, available through Sonora Quest Laboratories and performed by Quest Diagnostics. This test includes comprehensive analysis of the *BRCA1* and *BRCA2* genes. This letter documents the medical necessity for this test and, as such, provides information about the patient's medical history and treatment options.

The BRCAvantage® Comprehensive test is designed to assess the risk for BRCA-related Hereditary Breast and Ovarian Cancer Syndrome. For *BRCA1* mutation-positive individuals, the estimated cumulative risk of breast cancer by age 70 years is 55% to 65%.[1,2] For *BRCA2* mutation-positive individuals, it is 45% to 47%. Similarly, the cumulative risk of ovarian cancer by age 70 years is 39% for those with a *BRCA1* mutation and 11% to 17% for those with a *BRCA2* mutation. Mutations in these genes account for up to 15% of all ovarian cancer.[3] Additionally, individuals who carry a mutation and are diagnosed with cancer are at increased risk for future primary cancers. People who test positive for a *BRCA1* or *BRCA2* mutation have several options to decrease their risk of cancer.

Patient and Family Medical History

Significant aspects of my patient's personal and/or family history that are strongly suggestive of hereditary cancer are listed below.

Patient History

- ☐ The patient has a personal history of Type of Cancer diagnosed at age .
- ☐ The patient is of Ashkenazi Jewish descent.
- ☐ The patient does not have a personal history of cancer, but has a very strong family history of cancer as detailed below.
  - If the patient does not have a personal history of cancer, please indicate if any of the following apply:
    - ☐ The patient's affected relatives are deceased.
    - ☐ Patient does not have any contact with the affected relatives.
    - ☐ The affected relatives have refused genetic testing or have refused to share their testing history and/or test results with my patient.

Family History

- ☐ The patient has a family history that includes the following relatives and their conditions: *[for relatives, include both maternal and paternal sides of the family; cancers of concern are breast (male and female), ovarian, fallopian tube, primary peritoneal, prostate, and pancreatic; specify bilateral or multiple primary cancers]*

1. Relationship	Cancer	Age
2. Relationship	Cancer	Age
3. Relationship	Cancer	Age

- ☐ The patient has fewer than 2 informative female relatives (i.e.: first- or second-degree relative, on maternal or paternal side, who lived beyond age 45), which reduces the available family history information.
- ☐ A mutation was previously identified in the gene in the patient's blood relative Relationship .
- ☐ Other:

The relevant ICD-10 codes for this patient are .

Medical Necessity
I have determined that this test is medically necessary for the above-referenced patient. The American Society of Clinical Oncology recommends that genetic testing be offered to individuals with suspected inherited cancer risk for whom test results would aid in medical management decision-making. In addition, several professional societies, including those listed below, have published guidelines for managing patients with elevated cancer risks due to a gene mutation. Therefore, multiple professional organizations recommend BRCA testing based on the demonstrated clinical utility in the literature.[4-7]

- National Comprehensive Cancer Network
- American Society of Clinical Oncology

Ultimately, if a mutation is found in either the *BRCA1* or *BRCA2* genes, it would help clarify the patient's cancer risk and prompt a change in the patient's medical management due to the increased risk for breast, ovarian, and other cancers. Individuals with a hereditary cancer syndrome have specialized treatment options to decrease their risk of cancer, including increased surveillance, surgery, and chemoprevention. Therefore, test results are necessary in choosing the most appropriate course of treatment and/or surveillance for this patient. A positive result will provide a genetic diagnosis, which would help ensure my patient is managed appropriately.

Management changes may include:

- More aggressive surgical management of cancer
- Increased surveillance for breast cancer (such as breast MRI or starting screening at an earlier age)
- Risk-reducing surgery (such as prophylactic bilateral mastectomy or prophylactic bilateral salpingo-oophorectomy)
- Chemoprevention
- Other:

Informed Consent
The patient has provided informed consent after being counseled about the cancer risks associated with *BRCA1* and *BRCA2* mutations, the meaning of possible test results, and available treatment options.

I am specifying Quest Diagnostics as the performing laboratory because Quest Diagnostics has extensive experience in molecular genetics and offers a highly-sensitive and cost-effective test for hereditary breast and ovarian cancer.

Please contact me at Phone Number if you have any additional questions.

Thank you,
Physician Name, MD

References

1. Antoniou A, Pharoah PDP, Narod S, et al. Average risks of breast and ovarian cancer associated with *BRCA1* or *BRCA2* mutations detected in case series unselected for family history: a combined analysis of 22 studies. *Am J Hum Genet*. 2003;72:1117-1130.
2. Chen S, Parmigiani G. Meta-analysis of BRCA1 and BRCA2 penetrance. J Clin Oncol. 2007;25:1329-1333.
3. Pal T, Permuth-Wey J, Betts JA, et al. BRCA1 and BRCA2 mutations account for a large proportion of ovarian carcinoma cases. Cancer. 2005;104:2807-2816.
4. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology. Genetic/familial high-risk assessment: breast and ovarian. V4.2013. http://www.nccn.org/professionals/physician_gls/pdf/genetics_screening.pdf. Accessed August 15, 2013.
5. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 103: Hereditary breast and ovarian cancer syndrome. *Obstet Gynecol*. 2009;113:957-966.
6. American Society of Breast Surgeons. Position statement on *BRCA* genetic testing for patients with and without breast cancer. https://www.breastsurgeons.org/statements/PDF_Statements/BRCA_Testing.pdf. Updated September 30, 2012. Accessed August 26, 2013.
7. U.S. Preventive Services Task Force. Genetic risk assessment and *BRCA* mutation testing for breast and ovarian cancer susceptibility. http://www.uspreventiveservicestaskforce.org/uspstf/uspsbrgen.htm#update. Accessed August 15, 2013.