Genetic Testing For Hereditary Breast and/or Ovarian Cancer Screening (HBOC)

Description:

Genetic testing for hereditary breast and/or ovarian cancer (HBOC) syndrome is otherwise known as BRCA1 and BRCA2 testing. BRCA1 and BRCA2 belong to a class of genes known as tumor suppressors. The genes normally ensure stability of DNA and help prevent uncontrolled cell growth. Mutations of the BRCA1 and BRCA2 genes have been linked to the development of hereditary breast and ovarian cancer. HBOC is conducted to detect mutations that increase the risk of breast and ovarian cancer.

Policy/Criteria:

HBOC is only considered a covered benefit when the member meets the risk factors as outlined in this document. Total Health Care follows the recommendation of the U.S. Preventive Services Task Force (USPSTF) as it relates to the “grade D recommendation” against routine referral for BRCA1 or BRCA2 testing for women whose family history is not associated with an increased risk for deleterious mutation of the breast cancer susceptibility gene; and the “grade B recommendation” which recommends that women whose family history is associated with an increased risk for deleterious mutations in BRCA1 or BRCA2 genes be referred for genetic counseling and evaluation for BRCA testing.

Definitions: Please note, for the purpose of this Policy/Criteria:

1. Close blood relatives are defined as follows:
   a. First degree relatives include parents, siblings and offspring or Second degree relatives include half-brothers/sister, aunts/uncles, grandparents and nieces/nephews all on the same side of the family
   b. Third degree relatives include first cousins and great grandparents all on the same side of the family

2. A breast cancer diagnosis includes either invasive or non-invasive (ductal carcinoma in situ) types.
3. Ovarian cancer also includes fallopian tube cancers and primary peritoneal carcinoma.
4. Persons are NOT considered to have a limited family history unless they have fewer than two first-degree second-degree female relatives, on the same side of the family that lived to age 45.
5. Documentation of personal and family history should be in the contemporaneous medical records submitted with the testing request.
6. For the statements that include age guidelines, a person is considered to be 45 years of age up until the day before the 46th birthday, and a person is considered to be 50 years of age up until the day before their 51st birthday.

Administrative Criteria:

1. Prior authorization by the Medical Director
2. Depending on the Product line, a referral from the member’s Primary Care Physician (PCP) may be required for submission with supporting medical documentation accompanying the request. Documentation must include the following:
a. Plan ID#
   b. In network Genetics Alliance provider to perform the test
   c. Applicable ICD-9 diagnoses and CPT codes, preventative diagnosis codes and modifiers
   d. Proof of patient education
   e. Explanation of how genetics affects cancer susceptibility
   f. Patient must give informed consent
   g. Counseling regarding therapeutic options, including limitations

3. Genetic counseling is required prior to and after genetic testing for BRCA mutations in order to inform persons being tested about the advantages and limitations of a specific genetic test as applied to a unique person.

4. Total Health Care requires prior approval from requesting specialist before specimen is sent to genetic laboratory.

5. Requesting physician must provide the Health Plan with geneticist findings and recommendations.

Clinical Criteria:

BRCA1 and BRCA2 testing is proven for women with a personal history of breast cancer in the following situations:

1. Breast cancer diagnoses at age 45 or younger with or without family history OR
2. Breast cancer diagnosed at age 50 or younger with:
   A. At least one close blood relative with breast cancer at age 50 or younger OR
   B. At least one close blood relative with ovarian cancer OR
   C. Limited family history

3. Breast cancer diagnosed at any age with:
   A. Personal history of ovarian cancer OR
   B. At least two close blood relatives on the same side of the family with breast cancer and/or ovarian cancer at any age OR
   C. Two breast primaries in a single individual with at least one close blood relative with breast cancer diagnosed at age 50 years or younger; OR
   D. Two breast primaries in a single individual with at least one close blood relative with ovarian cancer; OR
   E. Two breast primaries, when first breast cancer diagnosis occurred prior to age 50, OR
   F. Close male blood relative with breast cancer; OR
   G. At least one close blood relative that has a BRCA1 or BRCA2 mutation; OR
   H. Ashkenazi Jewish or ethnic groups associated with higher mutation frequency such as Icelandic, Swedish, or Hungarian descent

I. BRCA1 and BRCA2 testing is proven for women with a personal history of ovarian cancer.

II. BRCA1 and BRCA2 testing is proven for men and women without a personal history of breast or ovarian cancer in the following situations:

   1. Persons with three or more affected first-degree or second-degree blood relatives on the same side of the family with breast or ovarian cancer, irrespective of age at diagnosis; OR
   2. Persons with two first-degree or second-degree relatives with:
      A. Ovarian cancer; OR
      B. Breast cancer, one or whom was diagnosed at age 50 or younger; OR
3. Persons with one or more first-degree or second-degree relatives with ovarian cancer and one or more first-degree or second-degree blood relatives on the same side of the family with breast cancer at any age/\textit{OR}

4. Persons with one or more first-degree or second-degree relatives with:

   A. Multiple primary or bilateral breast cancers in a single individual \textit{and} another first-degree or second-degree relative on the same side of the family with breast cancer diagnosed at age 50 years or younger; \textit{OR}

   B. Multiple primary or bilateral breast cancers in a single individual and another first-degree or second-degree blood relative on the same side of the family with ovarian cancer; \textit{OR}

   C. Close male blood relatives with breast cancer; \textit{OR}

   D. A known BRCA1 or BRCA2 mutation; \textit{OR}

   E. Breast cancer or ovarian cancer at any age in an individual of Ashkenazi Jewish, Icelandic, Swedish or Hungarian decent

III. BRCA1 and BRCA2 testing is proven for men with a personal history of breast cancer

IV. BRCA1 and/or BRCA2 testing is unproven for all other indications including screening of breast or ovarian cancer or for risk assessment of other cancers. While the BRCA mutation is known to be associated with other cancers such as prostate, pancreas and melanoma, as part of the Hereditary Breast Ovarian Cancer Syndrome (HBOC), BRCA testing is not indicated when one of these cancers is isolated in the family

\textbf{Applicable Codes:}

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

\begin{tabular}{|c|l|}
\hline
\textbf{CPT® Code} & \textbf{Description} \\
\hline
S3818 & Complete gene sequence analysis; BRCA1 gene \\
S3819 & Complete gene sequence analysis; BRCA2 gene \\
S3820 & Complete BRCA1 and BRCA2 gene sequence analysis for susceptibility to breast and ovarian cancer \\
S3822 & Single-mutation analysis (in individual with a known BRCA1 or BRCA2 mutation in the family) for susceptibility to breast and ovarian cancer \\
S3823 & Three-mutation BRCA1 and BRCA2 analysis for susceptibility to breast and ovarian cancer in Ashkenazi individuals \\
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\textbf{ICD-9 Code} & \textbf{Description} \\
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158.8 & Malignant neoplasm of specified parts of peritoneum \\
158.9 & Malignant neoplasm of peritoneum, unspecified \\
174.0 – 174.9 & Malignant neoplasm of female breast \\
175.0 – 175.9 & Malignant neoplasm of male breast \\
183.0 & Malignant neoplasm of ovary \\
198.6 & Secondary malignant of neoplasm of ovary \\
198.81 & Secondary malignant of neoplasm of breast \\
233.0 & Carcinoma in situ of breast \\
238.3 & Neoplasm of uncertain behavior of breast \\
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\end{tabular}
### Preventative Diagnosis Code

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<tr>
<td>V10.41</td>
<td>Personal history of malignant neoplasm of cervix uteri</td>
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<td>V10.43</td>
<td>Personal history of malignant neoplasm of ovary</td>
</tr>
<tr>
<td>V10.44</td>
<td>Personal history of malignant neoplasm of other female genital organs</td>
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<td>V16.3</td>
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### Modifier

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<td>0B</td>
<td>BRCA2 (Hereditary breast cancer)</td>
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### Exclusions:

1. Screening in the general population
2. No personal history of breast or ovarian cancer, except as noted above
3. Under 18 years of age

Adopted 10/2010

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**Cited Works**


4. Same as #3
5. Same as #3
6. Same as #3
