Genetic Testing for Breast and/or Epithelial Ovarian Cancer Susceptibility

Covered Service: Yes

Prior Authorization Required: Prior authorization is not required for BRCA1 and BRCA2 testing.

Additional Information: Genetic testing is covered for a WellFirst Health member if the test results provide a direct medical benefit or guides reproductive decision-making for the WellFirst Health member. See Genetic Testing MP9012 for additional information.

Pre and post-test genetic counseling is required for any individual undergoing genetic testing for hereditary breast and ovarian cancer syndromes.

Allowed once per lifetime in adults 18 years of age or older.

A first-degree relative is defined as an individual’s parents, full siblings, and children.

A second-degree relative is defined as an individual’s grandparents, grandchildren, aunts, uncles, nephews, nieces and half-siblings.

A third-degree relative is defined as first cousins, great-aunts, great-uncles, great-grandchildren, or great-grandparents.

WellFirst Health Medical Policy:

**BRCA1 and BRAC2 – Personal History of Cancer**

1.0 Personal history of epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer; OR

2.0 Personal history of male breast cancer; OR

3.0 Personal history of pancreatic cancer; OR

4.0 Personal history of metastatic prostate cancer; OR

5.0 Personal history of high-grade prostate cancer (Gleason score ≥7) at any age with ANY of the following:
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5.1 One or more close blood relatives with breast cancer (diagnosed at 50 or younger); OR

5.2 Invasive ovarian cancer; OR

5.3 Pancreatic cancer; OR

5.4 Metastatic prostate cancer; OR

5.5 Ashkenazi Jewish ancestry

6.0 BRCA1/BRCA2 pathogenic/likely variant detected by tumor profiling on any tumor type in the absence of germline pathogenic/likely pathogenic variant analysis.

7.0 Personal history of breast cancer and one or more of the following indications:

7.1 Breast cancer diagnosed at age 45 years or younger; OR

7.2 Breast cancer is diagnosed at age 46-50 years; and ANY of the following indications:

7.2.1 At least one close blood relative with breast cancer at any age; OR

7.2.2 At least one close blood relative with high-grade prostate cancer (Gleason score ≥7); OR

7.2.3 Diagnosed with two primary breast cancers (includes bilateral disease or cases where there are two or more clearly separate ipsilateral primary tumors) with first primary diagnosed at age 50 years or younger; OR

7.2.4 Unknown or limited family history (e.g., fewer than two first- or second degree female relatives or female relatives surviving beyond 45 years in the relevant maternal and/or paternal lineage).

7.3 Breast cancer is diagnosed at age 60 years or younger with a triple negative breast cancer; OR

7.4 Breast cancer is diagnosed at any age with ANY of the following indications:

7.4.1 Two or more close relatives on the same side of the family with breast cancer at any age; OR

7.4.2 One close blood relative with breast cancer diagnosed at any age 50 years or younger; OR

7.4.3 One close blood relative with epithelial ovarian cancer, fallopian tube, or primary peritoneal cancer; OR

7.4.4 One or more close male blood relatives with breast cancer; OR

7.4.5 One or more close male blood relatives with metastatic prostate cancer; OR
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7.4.6 One or more blood relatives with pancreatic cancer

7.5 Ashkenazi Jewish ancestry

**BRCA1 and BRAC2 – No Personal History/Family History Only**

8.0 Testing of an individual without a cancer diagnosis is not medically necessary if an affected family member is available for testing.

9.0 Testing of an individual from a family with a known deleterious BRCA1/BRCA2 gene mutation; **OR**

10.0 No personal history of breast cancer or ovarian cancer however, family history increases risk with **ANY** of the following:

10.1 First or second degree blood relative with a history of breast cancer and **ANY** of the following:

10.1.1 Diagnosed at age 45 or younger; **OR**

10.1.2 Diagnosed at age 50 or younger with a least 1 additional close blood relative with **ANY** of the following:

10.1.2.1 Breast cancer at any age; **OR**

10.1.2.2 Pancreatic cancer at any age; **OR**

10.1.2.3 Prostate cancer (Gleason score ≥7).

10.1.3 Diagnosed with two primary breast cancers (includes bilateral disease or cases where there are two or more clearly separate ipsilateral primary tumors) with first primary diagnosed at age 50 years or younger; **OR**

10.1.4 Diagnosed at age 60 or younger with a triple negative breast cancer; **OR**

10.1.5 Diagnosed at age 50 or younger with unknown or limited family history (e.g. fewer than two first- or second degree female relatives or female relatives surviving beyond 45 years in the relevant maternal and/or paternal lineage); **OR**

10.1.6 Diagnosed at any age and there are at least **2 or more** relatives with breast cancer, pancreatic cancer, or prostate cancer (Gleason score ≥7) at any age; **OR**

10.1.7 Diagnosed at any age with a least one close blood relative with breast cancer at age 50 or younger; **OR**

10.1.8 Diagnosed at any age with at least one close blood relative with invasive ovarian cancer, fallopian tube, or primary peritoneal cancer; **OR**

10.1.9 Close male blood relative with breast cancer; **OR**

10.1.10 Individual with Ashkenazi Jewish descent.
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10.2 First- or second-degree blood relative with a history of invasive ovarian, fallopian tube, or primary peritoneal cancer; OR
10.3 First- or second-degree relative with a history of male breast cancer; OR
10.4 First- or second-degree relative with a history of prostate cancer (Gleason ≥7) at any age with one or more close blood relatives with one or more of the following:
   10.4.1 Breast cancer (diagnosed at 50 or younger); OR
   10.4.2 Invasive ovarian cancer; OR
   10.4.3 Two or more relatives with breast, pancreatic cancer or prostate cancer (Gleason ≥7) at any age.

10.5 First- or second-degree relative with a history of pancreatic cancer at any age with at least one or more close blood relative with one or more of the following:
   10.5.1 Breast cancer (diagnosed at 50 or younger); OR
   10.5.2 Invasive ovarian cancer; OR
   10.5.3 Two or more relatives with breast, pancreatic cancer or prostate cancer (Gleason≥7) at any age.

10.6 First- or second-degree relative with a history of pancreatic cancer at any age with Ashkenazi Jewish descent; OR
10.7 Third-degree blood relative with breast and/or invasive ovarian/fallopian tube/primary peritoneal cancer with two or more close blood relatives with breast (at least one diagnosed at or prior to age 50) and/or invasive ovarian/fallopian tube/primary peritoneal cancer.

11.0 Genetic testing for high-risk breast cancer genes (e.g. CDH1, PALB2, PTEN, STK11, TP53) either individually or as a panel requires prior authorization may be indicated when ALL of the following are present:

11.1 Age 18 years or older; AND

11.2 Personal history increases risk of hereditary breast cancer, as indicated by 1 or more of the following:
   11.2.1 Personal history of female breast cancer and 1 or more of the following:
      11.2.1.1 Diagnosed at age 45 years or younger;
      11.2.1.2 Diagnosed at age 50 years or younger; and 1 or more of the following:
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11.2.1.2.1. One additional breast cancer primary diagnosed at any age;
11.2.1.2.2. One more close blood relatives with breast cancer diagnosed at any age;
11.2.1.2.3. One or more relatives with prostate cancer (Gleason score of 7 or greater);
11.2.1.2.4. Unknown or limited family history

11.2.1.3 Diagnosed at age 60 years or younger with triple-negative breast cancer

11.2.1.4 Diagnosed at any age, and **1 or more** of the following:

**11.2.1.4.1.** One additional primary diagnosed at any age, and one or more close blood relatives with breast cancer at any age;

11.2.1.4.2. One or more close blood relatives with breast cancer diagnosed at age 50 years or younger;

11.2.1.4.3. One or more close blood relatives with ovarian cancer diagnosed at any age;

11.2.1.4.4. One or more close blood relatives with pancreatic cancer diagnosed at any age;

11.2.1.4.5. One close male blood relative with breast cancer;

11.2.1.4.6. One or more close male blood relatives with metastatic prostate cancer diagnosed at any age;

11.2.1.4.7. Two or more additional breast cancer primaries diagnosed at any age;

11.2.1.4.8. Two or more close blood relatives with breast cancer diagnosed at any age

11.2.1.5 Ethnicity associated with deleterious mutations, including Ashkenazi Jewish, Icelandic, Hungarian, Swedish, and Dutch

11.2.2 Personal history of male breast cancer

12.0 WellFirst Health considers the following genes not medically necessary for breast and/or ovarian cancer susceptibility testing including but not limited to: ATM, BARD1, BRIP1, CHEK2, EPCAM, FANCC, MLH1, MRE11A, MSH2, MUTYH, NBN, NF1, PMS2, RAD50, RAD51C, RAD51D, SLX4, SMARCA4, and XRCC2.
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**CPT/HCPCS Codes Related to MP9478**

The list of codes (and their descriptors, if any) is provided for informational purposes only and may not be all inclusive or current. Listing of a code in this medical policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member’s policy of health coverage with WellFirst Health. Inclusion of a code above does not imply any right to reimbursement or guarantee claim payment. Other medical policies may also apply.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>81162</td>
<td>BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis</td>
</tr>
<tr>
<td>81163</td>
<td>BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis</td>
</tr>
<tr>
<td>81164</td>
<td>BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (e.g., detection of large gene rearrangements)</td>
</tr>
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</tr>
<tr>
<td>81167</td>
<td>RCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)</td>
</tr>
<tr>
<td>81212</td>
<td>BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants</td>
</tr>
<tr>
<td>81215</td>
<td>BRCA1 (breast cancer 1) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant</td>
</tr>
<tr>
<td>81216</td>
<td>BRCA2 (breast cancer 2) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis</td>
</tr>
<tr>
<td>81217</td>
<td>BRCA2 (breast cancer 2) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant</td>
</tr>
<tr>
<td>81432</td>
<td>Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer);</td>
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<tr>
<th>Genomic sequence analysis panel, must include sequencing of at least 14 genes, including ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, STK11, and TP53</th>
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</thead>
<tbody>
<tr>
<td>81433 Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11</td>
</tr>
</tbody>
</table>

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