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Genetic Testing for High-Penetrance Breast and/or Epithelial Ovarian Cancer Susceptibility MP9478

Covered Service: Yes

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

Additional Information: Genetic testing is covered for a Prevea360 Health Plan member if the test results provide a direct medical benefit or guides reproductive decision-making for the Prevea360 Health Plan member. See Genetic Testing MP9012 for additional information.

Pre and post-test genetic counseling may be required for any individual undergoing genetic testing for hereditary breast and ovarian cancer syndromes. Members under the care of an oncologist are not required to pursue genetic counseling if the oncologist will be counseling member regarding results.

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.

Testing of an individual without a cancer diagnosis should only be considered when an appropriate affected family member is unavailable for testing.

Prevea360 Health Plan Medical Policy:

Testing criteria for high-penetrance breast and/or ovarian cancer susceptibility genes which may include BRCA1, BRCA2, CDH1, PALB2, PTEN, TP53 and other genes (14.0 to 17.0) based on specific criteria outlined in the National Comprehensive Cancer Network (NCCN) guidelines with a category 1, 2A, or 2B level of evidence is considered medically necessary in the following scenarios:

1.0 Testing of individuals with any blood relative with a known pathogenic/likely pathogenic variant in a cancer susceptibility gene.

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2.0 Testing of individuals meeting the criteria below (3.0 to 9.0), but tested negative with previous limited testing (e.g. single gene and/or absent deletion duplication analysis) interested in pursuing multi-gene testing.

Personal History of Cancer

3.0 Breast cancer with at least **ONE** of the following:

- 3.1 Diagnosed at age ≤ 45 years;
- 3.2 Diagnosed at age 46-50 years with **ANY** of the following:
  - 3.2.1 Unknown or limited family history;
  - 3.2.2 A second breast cancer diagnosed at any age;
  - 3.2.3 One or more close blood relative with breast, ovarian, pancreatic, or prostate cancer at any age
- 3.3 Diagnosed at age ≤ 60 years with triple-negative breast cancer;
- 3.4 Diagnosed at any age with **ANY** of the following:
  - 3.4.1 Ashkenazi Jewish ancestry;
  - 3.4.2 One or more close blood relative with breast cancer at age ≤ 50 years or ovarian, pancreatic, metastatic or intraductal/cribriform histology, or high- or very-high risk group prostate cancer at any age;
  - 3.4.3 Three or more total diagnoses of breast cancer in member and/or close blood relatives
- 3.5 Diagnosed at any age with male breast cancer

4.0 Epithelial ovarian cancer (including fallopian tube cancer or peritoneal cancer) at any age;

5.0 Exocrine pancreatic cancer at any age;

6.0 Prostate cancer at any age with **ANY** of the following:

- 6.1 Metastatic, intraductal/cribriform histology, or high- or very-high-risk group prostate cancer at any age
- 6.2 Any NCCN risk group with **ANY** of the following family history:
  - 6.2.1 Ashkenazi Jewish ancestry;
  - 6.2.2 One or more close relative with **ANY** of the following:
    - 6.2.2.1 Breast cancer at age ≤ 50 years;
    - 6.2.2.2 Ovarian cancer at any age;
    - 6.2.2.3 Pancreatic cancer at any age
    - 6.2.2.4 Metastatic cancer at any age

6.2.2.5 Intraductal/cribriform prostate cancer at any age

6.2.3 Two or more close relatives with breast or prostate cancer (any grade) at any age

7.0 A mutation identified on tumor genomic testing that has clinical implications if also identified in the germline

8.0 Member who meets Li-Fraumeni syndrome testing criteria or Cowden syndrome/PTEN hamartoma tumor syndrome testing criteria

9.0 To aid in systemic therapy decision-making, such as HER2-negative metastatic breast cancer

No Personal History/Family History of Cancer Only

10.0 An affected or unaffected member with a first-or second-degree blood relative meeting **ANY** of the criteria listed above (3.0 to 9.0) (except members who meet criteria for systemic therapy decision-making)

11.0 An affected or unaffected member who otherwise does not meet the criteria above (3.0 to 9.0), but has a probability >5% of a BRCA1/2 pathogenic variant based on prior probability models (e.g. Tyrer-Cuzick, BRCAPro, CanRisk)

Other Testing Criteria

12.0 Testing may be considered medically necessary in **ANY** of the following scenarios:

12.1 Multiple primary breast cancers, first diagnosed between the ages of 50 and 65 years of age;

12.2 An Ashkenazi Jewish member;

12.3 An affected or unaffected member who otherwise does not meet any of the above criteria (3.0 to 9.0) but with a 2.5%-5% probably of BRCA1/2 pathogenic variant based on prior probability models (e.g. Tyrer-Cuzik, BRCAPro, CanRisk, l);

13.0 Dean Health Plan considers the following not medically necessary as there is low probability (<2.5%) that testing will have findings of documented utility in the following scenarios:

13.1 Women diagnosed with breast cancer at age >65 years, with no close relative with breast, ovarian, pancreatic, or prostate cancer;

13.2 Men diagnosed with localized prostate cancer with Gleason Score <7 and no close relative with breast, ovarian, pancreatic or prostate cancer.

Cancer Risk Management Genes

14.0 The following genes are considered medically necessary (based on NCCN Guidelines) for breast cancer risk and management including but not limited to:

ATM, BRCA1, BRCA2, BARD1, CDH1, CHEK2, , NF1, PALB2, PTEN, STK11, and TP53.

15.0 The following genes are **not medically necessary** (based on NCCN Guidelines) for breast cancer risk and management including but not limited to: BRIP1, CDKN2A, MSH2, MLH1, MSH6, PMS2, EPCAM, NBN, RAD51C, RAD51D

16.0 The following genes are considered medically necessary (based on NCCN Guidelines) for ovarian cancer risk and management including but not limited to: BRCA1, BRCA2, ATM, MSH2, BRIP1, MLH1, MSH6, PMS2, EPCAM, PALB2, RAD51C, RAD51D, and STK11.

17.0 The following genes **not medically necessary** (based on NCCN Guidelines) for ovarian cancer risk and management including but not limited to: BARD1, CDH1, CDKN2A, CHEK2, NBN, NF1, PTEN, and TP53.

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 Prevea360 Health Plan. Inclusion of a code above does not imply any right to reimbursement or guarantee claim payment. Other medical policies may also apply.

CPT Code	Description
0102U	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (17 genes [sequencing and deletion/duplication])
0103U	Hereditary ovarian cancer (eg, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA, and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated (24 genes [sequencing and deletion/duplication], EPCAM [deletion/duplication only])
0129U	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis and deletion/duplication analysis panel (ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, and TP53)
0131U	Hereditary breast cancer-related disorders (eg, hereditary breast

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CPT Code	Description
	cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (13 genes) (List separately in addition to code for primary procedure)
0132U	Hereditary ovarian cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (17 genes) (List separately in addition to code for primary procedure)
0134U	Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (18 genes) (List separately in addition to code for primary procedure)
0135U	Hereditary gynecological cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (12 genes) (List separately in addition to code for primary procedure
0137U	PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) mRNA sequence analysis (List separately in addition to code for primary procedure)
0138U	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) mRNA sequence analysis (List separately in addition to code for primary procedure)
81162	BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis
81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81164	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)
81165	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81166	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)
81167	RCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and

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CPT Code	Description
	ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)
81212	BRCA1, BRCA2 (breast cancer 1 and 2) (e.g., hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants
81215	BRCA1 (breast cancer 1) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant
81216	BRCA2 (breast cancer 2) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81217	BRCA2 (breast cancer 2) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant
81307	PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; full gene sequence
81308	PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; known familial variant
81432	Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); 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
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

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