

Hereditary Breast and/or Ovarian Cancer Susceptibility Panels

A hereditary breast and/or ovarian cancer susceptibility panel includes genes that are associated with an inherited susceptibility to breast cancer, ovarian cancer, or both.

- I. Genetic testing using a hereditary breast and/or ovarian cancer susceptibility panel is considered **medically necessary** when:
 - A. The panel includes, at a minimum, the following genes: *BRCA1*, *BRCA2*, **AND**
 - B. The member has one of the following:
 1. The member has a personal history of breast cancer \leq age 65, **OR**
 2. The member has a personal history of ovarian cancer (including fallopian tube cancer or peritoneal cancer), **OR**
 3. The member has a personal history of breast cancer, **AND**
 - a) One of the following:
 - (1) Ashkenazi Jewish ancestry, **OR**
 - (2) Male (sex assigned at birth), **OR**
 - (3) Triple-negative breast cancer, **OR**
 - (4) Pancreatic or ampullary cancer, **OR**
 - (5) Metastatic prostate cancer, **OR**
 - (6) High- or very-high-risk group prostate cancer, **OR**
 - (7) Multiple primary breast cancers (diagnosed synchronously or metachronously), **OR**
 - (8) The member has a close relative with any one of the following:
 - (a) Breast cancer diagnosed \leq age 50, **OR**

- (b) Male breast cancer, **OR**
 - (c) Ovarian cancer, **OR**
 - (d) Pancreatic cancer, **OR**
 - (e) Prostate cancer that is either metastatic, intermediate-risk or high- or very-high-risk group, **OR**
- b) There are ≥ 3 total diagnoses of breast cancer and/or prostate cancer (any grade) on the same side of the family including the member with breast cancer, **OR**
- 4. The member has a personal history of lobular breast cancer, **AND**
 - a) A personal or family history of diffuse gastric cancer, **OR**
 - 5. The member is unaffected or the member does not have a personal history of breast cancer that meets the above criteria, **AND**
 - a) The member has a first- or second-degree relative meeting any of the above criteria, **OR**
 - b) The member's probability of having a *BRCA1* or *BRCA2* pathogenic variant is greater than 2.5% based on prior probability models (e.g., Tyrer-Cuzick, BRCAPro, CanRisk), **OR**
 - 6. The member has a personal history of breast cancer, **AND**
 - a) The member has metastatic breast cancer and is being considered for systemic treatment using PARP inhibitors, **OR**
 - b) The member has HER2-negative breast cancer and is being considered for adjuvant treatment with olaparib.
- II. Genetic testing using a STAT hereditary breast cancer panel is considered **medically necessary** when:
- A. The member meets any of the above criteria, **AND**

- B. The member requires a rapid turn-around-time for decision making related to surgical interventions or treatment.
- III. *BRCA1/BRCA2* mRNA sequencing analysis in genes associated with breast and/or ovarian cancers for the interpretation of variants of unknown significance is considered **investigational** because it is typically either considered an existing component of the genetic testing process for quality assurance or follow up testing without proven utility.
- IV. Genetic testing using a hereditary breast and/or ovarian cancer susceptibility panel is considered **investigational** for all other indications.

DEFINITIONS

1. **Breast cancer** is a term that applies to patients with invasive cancer or ductal carcinoma in situ (DCIS).
2. **Close relatives** include first, second, and third degree blood relatives:
 - a. **First-degree relatives** are parents, siblings, and children
 - b. **Second-degree relatives** are grandparents, aunts, uncles, nieces, nephews, grandchildren, and half siblings
 - c. **Third-degree relatives** are great grandparents, great aunts, great uncles, great grandchildren, and first cousins
3. **High-risk prostate cancer** is defined by the NCCN Prostate Cancer Guidelines (1.2025) as an individual who has one or more of the following high-risk features, but does not meet criteria for very-high-risk prostate cancer.
 - a. cT3-cT4a
 - b. Grade Group 4
 - c. PSA > 20ng/ml

4. **Very-high-risk prostate cancer** is defined by NCCN Prostate Cancer Guidelines (1.2025) as an individual who has at least two of the following:
 - a. cT3-cT4
 - b. PSA >40 ng/mL
 - c. Grade Group 4 or 5

REFERENCES

1. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Genetic/Familial High-Risk Assessment: Genetic/Familial High-Risk Assessment: Breast, Ovarian, Pancreatic, and Prostate. Version 2.2025. https://www.nccn.org/professionals/physician_gls/pdf/genetics_bop.pdf.
2. Bedrosian I, Somerfield MR, Achatz MI, et al. Germline Testing in Patients With Breast Cancer: ASCO-Society of Surgical Oncology Guideline. J Clin Oncol. 2024;42(5):584-604. doi:10.1200/JCO.23.02225