Genetic Testing for Breast and Ovarian Cancer

Plan: AmeriHealth Caritas Louisiana

Clinical Policy ID: CCP.4012

Recent review date: **2/2023**

Next review date: **5/2024**

Policy contains: Breast cancer; Ovarian cancer; Genetic testing; BRCA1; BRCA2; cancer-affected; cancer-unaffected; LDH Provider Policy.

AmeriHealth Caritas Louisiana has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Louisiana's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by AmeriHealth Caritas Louisiana when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Louisiana's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Louisiana's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Louisiana will update its clinical policies as necessary. AmeriHealth Caritas Louisiana's clinical policies are not guarantees of payment.

Policy statement

Genetic testing is clinically proven and, therefore, medically necessary for BRCA1 and BRCA2 mutations in cancer-affected and cancer-unaffected individuals when the following criteria **are** met:

Individuals meeting one or more of the below criteria are considered eligible.

- Individuals with any blood relative with a known BRCA1/BRCA2 mutation;
- Individuals meeting the criteria below but with previous limited testing (eg, single gene and/or absent deletion duplication analysis) interested in pursuing multi-gene testing;
- Individuals with a personal history of cancer, defined as one or more of the following:
    - Breast cancer and one or more of the following:
        - Diagnosed age ≤45 years; or
        - Diagnosed at age 45—50 years with:
            - Unknown or limited family history; or
            - A second breast cancer diagnosed at any age; or
            - ≥1 close blood relative* with breast, ovarian, pancreatic, or high-grade (Gleason score ≥7) or intraductal prostate cancer at any age
        - Diagnosed at age ≤60 years with triple negative (ER–, PR–, HER2–) breast cancer;
        - Diagnosed at any age with:

                - Ashkenazi Jewish ancestry; or
                - ≥1 close blood relative* with breast cancer at age ≤50 years or ovarian, pancreatic, or metastatic or intraductal prostate cancer at any age; or
                - ≥3 total diagnoses of breast cancer in patient and/or close blood relatives*
            - Diagnosed at any age with male breast cancer; or
            - Epithelial ovarian cancer (including fallopian tube cancer or peritoneal cancer) at any age;
        - Exocrine pancreatic cancer at any age;
        - Metastatic or intraductal prostate cancer at any age;
        - High-grade (Gleason score ≥7) prostate cancer at any age with:
            - Ashkenazi Jewish ancestry; or
            - ≥1 close blood relative* with breast cancer at age ≤50 years or ovarian, pancreatic, or metastatic or intraductal prostate cancer at any age; or
            - ≥2 close blood relatives* with breast or prostate cancer (any grade) at any age
        - A mutation identified on tumor genomic testing that has clinical implications if also identified in the germline
        - To aid in systemic therapy decision-making, such as for HER2-negative metastatic breast cancer
- Individuals with a family history of cancer, including unaffected individuals, defined as one or more of the following:
    - An affected or unaffected individual with a 1st- or 2nd-degree blood relative meeting any of the criterion listed above (except individuals who meet criteria only for systemic therapy decision-making); or
    - An affected or unaffected individual who otherwise does not met criteria above but also has a probability >5% of a BRCA1/2 pathogenic variant based on prior probability models (eg, Tyer-Cuzick, BRCAPro, Pennll)

*For the purpose of familial assessment, close blood relatives include first-, second-, and third-degree relatives on the same side of the family (maternal or paternal):

- 1st-degree relatives are parents, siblings, and children;
- 2nd-degree relatives are grandparents, aunts, uncles, nieces, nephews, grandchildren, and half siblings; or
- 3rd-degree relatives are great-grandparents, great-aunts, great-uncles, great-grandchildren and first cousins.

Limitations:

None.

Exemptions:

None.

References

Louisiana Department of Health. 2012. Medicaid Professional Services Provider Manual. Genetic Testing for Breast and Ovarian Cancer, Chapter Five, Section 5.1. Issued **09/13/21.**

Policy updates

Initial review date: 3/1/2021

2/2023: Policy references updated.