BRCA Testing (BRACAnalysis_CDx; myChoice CDx) (Myriad)

Date of Origin: 08/29/2019 **Last Review Date: 02/26/2025** **Effective Date: 3/1/2025**

Dates Reviewed: 09/2019, 10/2020, 01/2021, 01/2022, 01/2023, 01/2024, 02/2025

Developed By: Medical Necessity Criteria Committee

I. Description

BRACAnalysis CDx, an example of germline BRCA testing, is an in vitro diagnostic device intended for the qualitative detection and classification of variants in the protein coding regions and intron/exon boundaries of the BRCA1 and BRCA2 genes using genomic DNA obtained from whole blood specimens collected in EDTA (FDA, 2014). Single nucleotide variants, small insertions, and deletions (indels) are identified by polymerase chain reaction (PCR) and Sanger sequencing. Large deletions and duplications in BRCA1 and BRCA2 are detected using multiplex PCR. Results of the test are used as an aid in identifying ovarian cancer patients with deleterious or suspected deleterious germline BRCA variants eligible for treatment with olaparib (Lynparza)). This assay is only performed at Myriad Genetic Laboratories, a single laboratory site located in Salt Lake City, UT.

myChoice® CDx , an example of somatic/tumor BRCA testing, is a next generation sequencing-based in vitro diagnostic test that assesses the qualitative detection and classification of single nucleotide variants, insertions and deletions, and large rearrangement variants in protein coding regions and intron/exon boundaries of the BRCA1 and BRCA2 genes and the determination of Genomic Instability Score (GIS) which is an algorithmic measurement of Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-scale State Transitions (LST) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. The results of the test are used to identify individuals with ovarian cancer who may be eligible for treatment with niraparib (Zejula).

II. Criteria:

A. **BRACAnalysis_CDx** will be covered to plan limitations for members, 18 years old or older who have one of the following:

   a. Ovarian cancer (including epithelial ovarian cancer, fallopian tube or primary peritoneal cancer) and **ALL** of the following;

      i. Have been treated with one of the following

         1. Three or more prior lines of chemotherapy
         2. First-line platinum-based chemotherapy and in complete or partial response

      ii. No previous testing for BRCA mutations

iii. Are being considered for treatment/maintenance with Lynparza or Rubraca

b. Metastatic, HER2 negative breast cancer and all of the following
   i. Previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting (regardless of family history)
   ii. No previous testing for BRCA mutations
   iii. Are being considered for treatment with Lynparza or Talzenna

c. Individuals with metastatic pancreatic carcinoma whose disease has not progressed following the first line of treatment and are being considered for maintenance treatment with olaparib (Lynparza)

d. Individuals with metastatic prostate cancer who are being considered for treatment with olaparib (Lynparza)

B. **myChoice CDx** will be covered to plan limitations for members who meet **ALL** the following criteria:
   a. 18 years old or older
   b. Have advanced epithelial ovarian cancer, fallopian tube or primary peritoneal cancer and ONE of the following:
      i. Have been treated with three or more lines of chemotherapy and are being considered for treatment with niraparib (Zejula)
      ii. Are in complete or partial response to two or more lines of platinum-based chemotherapy and are being considered for maintenance treatment with niraparib (Zejula)
      iii. Are being considered for first line maintenance treatment with Olaparib (Lynparza) and bevacizumab

III. Information Submitted with the Prior Authorization Request:

1. Chart notes
2. Previous treatments
3. Treatment plan

IV. CPT or HCPC codes covered:

Codes	Description
81162	BRCA1, BRCA2 (breast cancer 1 and 2) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis
0172U	Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score
No specific code	Olaparib (Lynparza), Talazoparib (Talzenna), Rucaparib (Rubraca), Niraparib (Zejula)

V. CPT or HCPC codes NOT covered:

Codes	Description
81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81166	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
81167	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements

VI. Annual Review History

Review Date	Revisions	Effective Date
9/25/2019	Criteria updated to the most recent NCCN guidelines and Myriad Inc. information	10/1/2019
10/28/2020	Annual Review: Updated the title "BRCA testing". Added myChoice CDx coverage guidelines and cpt code 0172U	11/2/2020
1/27/2021	Annual Review: BRACAnalysis CDx: Update to replace with the wording 'women' with 'individuals', as this would broaden coverage for breast, ovarian and prostate cancer. myChoice CDx: An update included adding an indication for using this test for advanced epithelial ovarian cancer, fallopian tube or primary peritoneal cancer when there is consideration for combination treatment using Lynparza and Bevacizumab	2/1/2021
1/26/2022	Annual Review: No changes	2/1/2022
01/25/2023	Annual Review: Grammar updates	2/1/2023
01/24/2024	Annual Review: No changes	2/1/2024
02/26/2025	Annual Review: Updated CPT codes relevant for this policy	3/1/2025

VII. References

1. Myriad Genetics. BRACAnalysis CDx. Technical Information Summary. Salt Lake City, UT: Myriad Genetics; 2014.
2. AstraZenica Pharmaceutics, LP. Lynparza (olaparib) capsules, for oral use. Prescribing Information. Reference ID: 3675412. Wilmington, DE: AstraZenica; revised December 2014.

3. U.S. Food and Drug Administration (FDA). BRACAnalysis CDx - P140020. Recently Approved Medical Devices. Silver Spring, MD: FDA; updated December 30, 2014.
4. U.S. Food and Drug Administration (FDA). FDA approves the first treatment for breast cancer with a certain inherited genetic mutation. FDA News Release. Silver Spring, MD: FDA; January 12, 2018. MolDX Myriad's BRACAnalysis_CDx Billing and Coding Guidelines
5. BRCA Mutations: Cancer risk and genetic testing. https://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet

Appendix 1 – Applicable Diagnosis Codes:

Codes	Description
C48.0-C48.8	Malignant neoplasm of retroperitoneum and peritoneum
	Malignant neoplasm of breast [HER2-negative]
	Malignant neoplasm of ovary
	Malignant neoplasm of fallopian tube

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC