MEDICAL POLICY	Genetic Testing: Hereditary Breast and Ovarian Cancer Genetic Testing (Medicare Only)
Effective Date: 08/01/2021  8/1/2021 Medical Officer Date	Medical Policy Number: 144 Medical Policy Committee Approved Date: 1/17; 5/17; 1/18; 2/19; 3/19; 9/19; 11/19; 4/2020; 12/2020; 5/2021

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare only

MEDICARE POLICY CRITERIA

Notes:

- Testing of an unaffected Medicare eligible individual or family member is not a covered Medicare benefit. Please see the Limitations section in the LCD L36163 for more information.
- BRCA1 and BRCA2 testing consists of full sequence and duplication/deletion analysis. This includes BART testing for large rearrangements. Please see Policy Guidelines and Billing Guidelines sections below.
- The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Service	Medicare Guidelines
BRCA1/BRCA2 Genetic Testing	• Local Coverage Determination (LCD): MolDX: BRCA1 and BRCA2 Genetic Testing (L36163)[1] • Local Coverage Article: Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing (A57355)[2]
Genetic Testing for Susceptibility to Breast or Ovarian Cancer with Multigene NGS Panels	National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2)[3]

	*Note: If test is not addressed in above NCD, refer to the "Multigene Panels***" section of L36163[1] for additional medical necessity criteria.*

Per the Medicare Policy Manual commercial medical policies may be applied to Medicare coverage determinations in the absence of an appropriate NCD, LCD, LCA, or CMS Coverage Manual. Therefore, the commercial medical policy, **Genetic Testing: Hereditary Breast and Ovarian Cancer (All Lines of Business Except Medicare)** *applies to any service not addressed in the guidelines above.*

POLICY GUIDELINES

BART testing for large rearrangements (e.g., large deletions and/or duplications) may be included and is covered as a component of BRCA1 and/or 2 testing when medical necessity criteria above are met.

BILLING GUIDELINES

Please refer to Local Coverage Article: Billing and Coding: MoIDX: BRCA1 and BRCA2 Genetic Testing (A57355)[2]

BART testing for large rearrangements (e.g., large deletions and/or duplications), billed with 81164 **OR** 81166 and/or 81167, may be denied as not covered when the medical necessity for hereditary breast or ovarian cancer testing above is not met.

When no specific CPT or HCPCS code exists for the panel, the provider is required to bill using an unlisted code. It is not appropriate for the provider to bill any of the tests in a panel separately as if they were performed individually. This is a misrepresentation of services performed and is not appropriate based on either CPT or CMS guidelines. In a "Healthcare Fraud Prevention Partnership" white paper published in May, 2018, CMS identified unbundling of lab panels as an example of fraudulent billing.

CPT/HCPCS CODES

Genetic testing for hereditary breast and/or ovarian cancer may include but is not limited to any of the CPT codes listed below. Additional codes may apply.

Medicare Only	
Prior Authorization Required	
0129U	Hereditary breast cancer–related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis and

	eletion/duplication analysis panel (ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, and TP53)
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)
0238U	Oncology (Lynch syndrome), genomic DNA sequence analysis of MLH1, MSH2, MSH6, PMS2, and EPCAM, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions
81162	BRCA1, BRCA2 (Breast Cancer 1 AND 2) (EG, 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) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81165	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81212	BRCA1, BRCA2 (Breast Cancer 1 AND 2) (EG, Hereditary breast and ovarian cancer) Gene analysis; 185delAG, 5385de AG, 5385insC, 6174delT variants
81215	BRCA1 (Breast Cancer 1) (EG, Hereditary breast and ovarian cancer) Gene analysis; known familial variant
81216	BRCA1 (Breast Cancer 2) (EG, Hereditary breast and ovarian cancer) Gene analysis; full sequence analysis
81217	BRCA1 (Breast Cancer 2) (EG, 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 (EG, 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 (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis and RNA analysis when performed, 5-50 genes (EG, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
81455	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm , DNA analysis and RNA analysis when performed, 51 or greater genes (EG, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL,

	NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
No Prior Authorization Required	
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])
0132U	Hereditary ovarian cancer - â€“ 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)
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)
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)
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then **prior-authorization is required.**	
81479	Unlisted molecular pathology procedure

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): MolDX: BRCA1 and BRCA2 Genetic Testing (L36163). Effective 12/04/2019. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36163. Accessed 3/24/2021.
2. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing (A57355). Effective 7/31/2020. https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=57355. Accessed 3/24/2021.
3. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2). Effective 1/27/2020. https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=372. Accessed 3/24/2021.