

Medicare Advantage Medical Policy



Nonprofit corporations and independent licensees
of the Blue Cross and Blue Shield Association

Germline Genetic Testing for BRCA1, BRCA2, and PALB2 for Hereditary Breast/Ovarian Cancer Syndrome and Other High-Risk Cancers – Medicare Advantage

Medicare Advantage Plan

☒ Medicare Plus BlueSM

☒ BCN AdvantageSM

UM Committee Approval Date: 3/18/2026

Effective Date: 4/18/2026

Description

Germline testing for Hereditary Breast and Ovarian Cancer (HBOC) syndrome, also referred to as genetic screening, aims to identify mutations in specific genes that increase the likelihood of developing breast and ovarian cancers. The BRCA1 and BRCA2 genes are the most well-established genetic markers for HBOC syndrome, with mutations in these genes significantly elevating an individual's risk of developing these cancers. Additionally, other genes such as PALB2, TP53, PTEN, and CDH1, may also be tested as they are associated with various cancer risks. Notably, the PALB2 gene, which plays a critical role in maintaining genomic stability through the repair of DNA double-strand breaks, has been identified as a significant risk factor for breast cancer, particularly in individuals with a family history of the disease.

Testing methods can include next-generation sequencing (NGS), gene panel testing, multiplex ligation-dependent probe amplification (MLPA), array comparative genomic hybridization (aCGH), whole exome sequencing (WES), and polymerase chain reaction (PCR). By testing mutations in these genes, individuals can better understand their risk of developing breast and ovarian cancers and take informed decisions about their health.

Related Medical Coverage Policies

- Genetic Cancer Susceptibility Panels Using Next Generation Sequencing – Medicare Advantage
- Genetic Testing - Assays of Genetic Expression in Tumor Tissue as a Technique to Help Guide Decision - Making in Patients with Breast Cancer – Medicare Advantage
- Genetic Testing for PTEN Hamartoma Tumor Syndrome – Medicare Advantage
- Genetic Testing - NGS of Multiple Genes (Panel) for Solid and Hematolymphoid Malignant Conditions – Medicare Advantage
- Genetic Testing (Single Nucleotide Variants) to Predict Risk of Nonfamilial Breast Cancer – Medicare Advantage

- GT-Germline and Somatic Biomarker Testing (Including Liquid Biopsy) for Targeted Treatment in Ovarian Cancer (BRCA1, BRCA2, Homologous Recombination Deficiency) – Medicare Advantage
- Germline Genetic Testing for Gene Variants Associated with Breast Cancer in Individuals at Moderate and High Breast Cancer Risk (e.g., CHEK2, ATM, BARD1, etc.) – Medicare Advantage

Policy Guidelines

Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network of Michigan (BCN) adhere to guidance from the Centers for Medicare and Medicaid Services (CMS), including when performing organization determinations for Medicare Advantage plan members. CMS Medicare statutes, regulations, manuals, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and other sub-regulatory guidance provide the clinical guidelines for coverage determinations, payment integrity functions, and all other uses by CMS regulations. When CMS Medicare guidance is silent, incomplete, or insufficient, CMS permits BCBSM/BCN to utilize “internal coverage criteria”, such as independent criteria, health plan policy research, LCD/LCAs outside the services area or research from independent medical research repositories (i.e., Hayes) for coverage policies 42 CFR § 422.101. BCBSM/BCN internal medical coverage policies are developed and based on current evidence in widely accepted treatment guidelines or clinical literature; in addition, they address how clinical benefits may or may not outweigh member harm.

Clinical review follows guidance provided in the BCBSM Medicare Advantage Coverage Determination Hierarchy policy, which may be found at

<https://www.bcbsm.com/providers/mpradmin/> by entering the policy name.

Coverage Guidance

To ensure consistency with coverage guidance, the Medicare statutes, regulations, coverage manuals, NCD, LCD, and LCA should be reviewed and applied first. BCBSM/BCN internal coverage criteria should only be applied when CMS guidance is silent, incomplete, or insufficient for a code.

Apart from durable medical equipment (DME), Medicare Administrative Contractor (MAC) jurisdiction for the purpose of clinical determination is based upon place of service. The place of service for laboratory testing is defined as the geographic location of the reference laboratory. Non-jurisdictional LCD/LCAs may not be utilized for a determination unless they have been specifically identified as internal coverage criteria by the policy. Alternatively, jurisdiction for DME MAC is determined by the member place of residence. Please see CMS Medicare Administrative Contractors (MAC) table for state MAC assignments below.

CMS Guidance	Additional Guidance
National Coverage Determinations 90.2 - Next Generation Sequencing 310.1 - Routine Costs in Clinical Trials For additional information related to clinical trials related to genetic breast cancer testing Please refer to this URL: https://clinicaltrials.gov	BCBSM/BCN will follow CMS guidance as the primary source for coverage determinations. However, in instances where CMS guidance is silent, incomplete, or insufficient for a particular code, BCBSM/BCN internal coverage criteria will be applied to ensure consistent and informed decision-making.

Local Coverage Determinations and Articles**WPS**

L39040, A58756 - MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer*

A55224 - MoIDX: Germline testing for use of PARP inhibitors*

L36807, A57772 - MoIDX: Molecular Diagnostic Tests (MDT)*

L38429, A57100 - MoIDX: Repeat Germline Testing*

CGS

L39017, A58734 - MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer*

A54689 - MoIDX: Germline testing for use of PARP inhibitors*

L36021, A56973 - MoIDX: Molecular Diagnostic Tests (MDT)*

L38288, A57141 - MoIDX: Repeat Germline Testing*

First Coast

L36449, A57449 - BRCA1 and BRCA2 Genetic Testing

L39367, A59123 - Genetic Testing for Oncology

L34519, A57451- Molecular Pathology Procedures

A58918 - Molecular Pathology and Genetic Testing

NGS

L35000, A56199 - Molecular Pathology Procedures

Noridian JE

A55294 - MoIDX: Germline testing for use of PARP inhibitors*

L35160, A57526 - MoIDX: Molecular Diagnostic Tests (MDT)*

L38351, A57331 - MoIDX: Repeat Germline Testing*

L38972, A58679 - MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer*

Noridian JF

A55295 - MoIDX: Germline testing for use of PARP inhibitors*

L36256/ A57527 - MoIDX: Molecular Diagnostic Tests (MDT)*

L38353, A57332 - MoIDX: Repeat Germline Testing*

L38974, A58681 - MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer*

Novitas

L36715, A56542 - BRCA1 and BRCA2 Genetic Testing

L39365, A59125 - Genetic Testing for Oncology

L35062 - Biomarkers Overview

A58917 - Molecular Pathology and Genetic Testing

Palmetto

L38966 - MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer*

In such cases, please refer to the relevant BCBSM/BCN policy for guidance:

Germline Genetic Testing for BRCA1, BRCA2, and PALB2 for Hereditary Breast/Ovarian Cancer Syndrome and Other High-Risk Cancers

To access this policy, please visit the BCBSM Medical Policy Router Search page at

<https://www.bcbsm.com/providers/mpradmin/>

and enter the policy name in the search field.

A54338 - MoIDX: Germline testing for use of PARP inhibitors*	
L35025, A56853 – MoIDX: Molecular Diagnostic Tests (MDT)*	
L38274, A58017 - MoIDX: Repeat Germline Testing*	

Code	Description
81162	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis (i.e., detection of large gene rearrangements) [BRCAAnalysis CDx™, Myriad Genetics]
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 (i.e., 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	BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (i.e., detection of large gene rearrangements)
81212	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants
81215	BRCA1 (BRCA1, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant
81216	BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81217	BRCA2 (BRCA2, DNA repair associated) (e.g., hereditary breast and ovarian cancer) gene analysis; known familial variant
81307	PALB2 (partner and localizer of BRCA2) (e.g., breast and pancreatic cancer) gene analysis; full gene sequence
81308	PALB2 (partner and localizer of BRCA2) (e.g., 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, hereditary pancreatic cancer, hereditary prostate cancer); genomic sequence analysis panel, 5 or more genes, interrogation for sequence variants and copy number variants [BRCANext®, Ambry Genetics®]
81479	Unlisted molecular pathology procedure [MyRisk® Hereditary Cancer Test, Myriad Genetics Laboratories, Inc]
0102U	Hereditary breast cancer-related disorders (e.g., 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]) [BreastNext®, Ambry Genetics®]
0103U	Hereditary ovarian cancer (e.g., 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]) [OvaNext®, Ambry Genetics®]
0129U	Hereditary breast cancer-related disorders (e.g., 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) [BRCAplus®, Ambry Genetics®]

CPT® codes, descriptions and materials are copyrighted by the American Medical Association (AMA).

HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

The above information is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document.

Please refer to the Medicare Coverage Database website at <https://www.cms.gov/medicare-coverage-database/search.aspx> for the most current applicable NCD, LCD, LCA, and CMS Online Manual System Transmittals.

CMS Medicare Administrative Contractors (MAC) Jurisdictions Guidance

Part A and Part B MAC Jurisdictions	
Wisconsin Physicians Service Insurance Corporation (WPS)	IA, IN, KS, MI, MO, NE
CGS Administrators, LLC	KY, OH
First Coast Service Options, Inc	FL, PR, US VI
National Government Services, Inc (NGS)	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI,
Noridian Healthcare Solutions, LLC, Jurisdiction JE	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
Noridian Healthcare Solutions, LLC, Jurisdiction JF	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
Novitas Solutions, Inc	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX,
Palmetto GBA	AL, GA, TN NC, SC, VA, WV
DME MAC Jurisdictions	
CGS Administrators, LLC, Jurisdictions JB and JC	AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NM, NC, OH, OK, Puerto Rico, SC, TN, TX, VA, Virgin Island, WI, WV
Noridian Healthcare Solutions, LLC, Jurisdictions JA and JD	AK, American Soamoa, AZ, CA, CT, DE, DC, Guam, HI, ID, IA, KS, MA, MD, ME, MO, MT, ND, NE, NH, NJ, NV, NY, Northern Mariana Islands, OR, PA, RI, SD, UT, VT, WA, WY

Important Reminder

BCBSM and BCN follow CMS Medicare coverage guidance to limit coverage to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Medicare Advantage Medical Policies list the criteria BCBSM and BCN use to decide which medical services are considered “reasonable and necessary” when Medicare coverage rules are not fully developed, or as otherwise may permitted by CMS Medicare regulations. Individual member benefit plan documents, such as the Evidence of Coverage and Annual Notice of Change, as well as applicable laws govern benefit coverage, including any inclusion, exclusion, and/or other restrictions.

Medicare Advantage Medical policies are created when permitted by CMS Medicare regulations, reviewed regularly, and may be revised periodically. BCBSM/BCN Medical Policies are

proprietary and should not be copied or disseminated without the express, prior written approval of BCBSM. All providers are required to review applicable BCBSM reimbursement policies prior to claim submission and bill for covered services in accordance with those policies. Additionally, providers contracted with BCBSM or BCN's Medicare Advantage network(s) should review the provider manual for any additional claim submission requirements. Providers not contracted with BCBSM or BCN's Medicare Advantage network may be required to submit documentation to BCBSM, BCN, or its delegated entity supporting billed claims, including but not limited to applicable medical records.

Note: U.S. Food and Drug Administration (FDA) approval for a specific indication or the issuance of a CPT code is not sufficient for a procedure to be considered medically reasonable and necessary. Similarly, the presence of a procedure/device code or payment amount for the service in the Medicare fee schedule does not necessarily indicate coverage. If a service is deemed not reasonable and necessary, to treat illness or injury for any reason (including lack of safety and efficacy because it is an experimental procedure, etc.), the procedure is considered not covered.

Disclaimer: This medical policy is not an authorization, certification, explanation of benefits, or a contract for the services, devices, or drugs that is referenced in the medical policy. Medical policies do not constitute medical advice and do not guarantee any results or outcomes or guarantee payment. The medical policy is not intended to replace independent medical judgment for the treatment of individuals. Treating physicians and health care providers are solely responsible for determining what care to provide to their patients. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another.

Pursuant to Section 1557 and Section 504, Blue Cross does not discriminate on the basis of race, color, national origin, age, disability, or sex (including sex characteristics, intersex traits; pregnancy or related conditions; sexual orientation; gender identity, and sex stereotypes). This includes our rules, benefit designs and medical policies.

BCBSM/BCN Medicare Advantage Policy History

Policy Effective Date	UM Committee Approval Date	Comments
08/17/2024	07/17/2024	Medicare Advantage policy established
04/19/2025	03/19/2025	Annual Review: MA policy foundational language updated. Adoption of JUMP policy updates.
04/18/2026	03/18/2026	Annual Review: Reformatted guidance and code tables. Adoption of JUMP policy updates.