



Breast Cancer Genetic Testing (Tier 1 vs Tier 2)

Purpose

This policy is intended to ensure correct provider reimbursement and serves only as a general resource regarding Molina Healthcare's reimbursement policy for the services described in this policy. It is not intended to address every aspect of a reimbursement situation, nor is it intended to impact care decisions. This policy was developed using nationally accepted industry standards and coding principles. In a conflict, federal and state guidelines, as applicable, and the member's benefit plan document supersede the information in this policy. Also, to the extent of conflicts between this policy and the provider contract language, the Provider contract language will prevail. Coverage may be mandated by applicable legal requirements of a State, the Federal government or the Centers for Medicare and Medicaid Services (CMS). References included were accurate at the time of policy approval. If there is a state exception, please refer to the state exception table listed below.

Policy Overview

When conducting molecular pathology tests, specific CPT codes are utilized to represent the corresponding tests. These codes are categorized into tier 1 and tier 2. Tier 1 codes are highly specific, representing only one gene or disease marker, whereas tier 2 codes generally represent groups of conditions that are uncommon and rare compared to those covered by tier 1 codes.

In adherence to payment integrity principles, it is essential to use the code that provides the highest specificity and accuracy to represent the test performed. For conditions represented by tier 2 codes, disease-specific precision is not feasible; hence, codes representing a group of conditions should be applied.

Tests commonly conducted for BRCA1 and BRCA2 genes pertain to breast, ovarian, fallopian tube, primary peritoneal, pancreatic, or prostate cancer. If any of these cancer diagnoses are present in a claim and BRCA1 and/or BRCA2 are being evaluated, tier 1 CPT codes must be used, rendering tier 2 codes unsuitable. Additionally, if these cancer diagnoses are included in a claim, unlisted codes (81479, 81599) should not be employed.

The BRCA gene test employs DNA analysis to identify harmful mutations in two breast cancer susceptibility genes: BRCA1 (Breast Cancer gene 1) and BRCA2 (Breast Cancer gene 2). When assigning CPT codes for BRCA1 and BRCA2 testing, it is crucial to ensure that the diagnosis codes align with medical necessity criteria. Molina Healthcare recommends reviewing the provided reference materials to determine the appropriate diagnosis codes for accurately assessing medical necessity.

Affected CPT codes: 81162-81167, 81212-81217, 81479, 81599.

Coverage is determined by the specific terms of the member's benefit plan

- **Tier 1 code:** Describes testing for a specific gene or HLA locus associated with a particular disease.
- **Tier 2 code:** Represents procedures that are generally performed in lower volumes compared to Tier 1 procedures (e.g., the incidence of the disease being tested is rare). These codes are organized by the level of technical resources required and the interpretive work conducted by the physician or other qualified health care professional. They are based on complexity, with each code potentially representing multiple rare conditions.

If an ICD-10 code for breast, ovarian, fallopian tube, primary peritoneal, pancreatic, or prostate cancer is on the claim, then Tier 1 codes (**81162-81167, 81212-81217**) should be used, and any Tier 2 codes on the same claim will be denied.

Code	Description- <u>Supported ICD10 (combined diagnosis list from CMS)</u>
C25.0	Malignant Neoplasm of head of pancreas

C25.1	Malignant Neoplasm of body of pancreas
C25.2	Malignant Neoplasm of tail of pancreas
C25.3	Malignant Neoplasm of pancreatic duct
C25.4	Malignant neoplasm of endocrine pancreas
Code	Description- Supported ICD10 (combined diagnosis list from CMS)
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
C48.1	Malignant neoplasm of specified parts of peritoneum
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast

C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast

Code	Description- <u>Supported ICD10 (combined diagnosis list from CMS)</u>
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast

C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast

Procedure Codes (CPT & HCPCS)

Tier 1 BRCA Codes

Code	Code Description
81212	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED), BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; 185DELAG, 5385INSC, 6174DELT VARIANTS
81215	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; KNOWN FAMILIAL VARIANT
81216	BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS
81217	BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; KNOWN FAMILIAL VARIANT
81162	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED), BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS AND FULL DUPLICATION/DELETION ANALYSIS (IE, DETECTION OF LARGE GENE REARRANGEMENTS)
81163	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED), BRCA2 (BRCA2, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS
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)
81165	BRCA1 (BRCA1, DNA REPAIR ASSOCIATED) (EG, HEREDITARY BREAST AND OVARIAN CANCER) GENE ANALYSIS; FULL SEQUENCE ANALYSIS
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)

Reimbursement Guidelines

Molina Healthcare covers BRCA1 and BRCA2 Genetic testing only when relevant signs, symptoms, or diseases are diagnosed. To request reimbursement for BRCA1 and BRCA2 Genetic Testing, it is essential to include the appropriate diagnosis codes. Incorrect submissions of diagnosis and procedure codes may result in Molina Healthcare reviewing, denying, and recovering any incorrectly paid claims.

Supplemental Information

Definitions

Term	Definition
CMS	the Centers for Medicare & Medicaid Services. It is a federal agency within the United States Department of Health and Human Services that administers the Medicare program and works in partnership with state governments to administer Medicaid, the Children's Health Insurance Program (CHIP), and health insurance portability standards.

State Exceptions

State	Exception
MI	This policy does not apply to MI providers

Documentation History

Type	Date	Action
Effective Date	11/20/2020	New Policy
Revised Date	10/18/2022	Updated links and added code descriptions
Revised Date	08/16/2023	Updated links, added 2023 CPT guideline page number- CS
Revision Date	12/12/2024	Verified Links, Updated Template and combined two policies

References

State	Exception
CMS	A57355: Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing:
CMS	A56199: Billing and Coding: Molecular Pathology Procedures
CMS	LCD L35000:
CMS	Article A58917: Billing and Coding: Molecular Pathology and Genetic Testing: Billing and Coding: Molecular Pathology and Genetic Testing
2021 CPT BOOK	Tier 2 Molecular Pathology Procedure Guidelines- Page 614
	<p>"Tier 2 molecular pathology codes "represent medically useful procedures that are generally performed in lower volumes than Tier 1 procedures (e.g., the incidence of the disease being tested is rare). They are arranged by level of technical resources and interpretive work by the physician or other qualified health care professional. [...]Use the appropriate molecular pathology procedure level code that includes the specific analyte listed after the code descriptor. If the analyte tested is not listed under one of the Tier 2 codes or is not represented by a Tier 1 code, use the unlisted molecular pathology procedure code, 81479."</p>
2022 CPT Book- Tier 2 Molecular Pathology Procedure Guidelines- Page 631	<p>"The following molecular pathology procedure (Tier 2) codes are used to report procedures not listed in the Tier 1 molecular pathology codes (81161, 81200-81383). They represent medically useful procedures that are generally performed in lower volumes than Tier 1 procedures (e.g., the incidence of the disease being tested is rare). They are arranged by level of technical resources and interpretive work by the physician or other qualified health care professional. The individual analyses listed under each code (i.e., level of procedure) utilize the definitions and coding principles preceding the Tier 1 molecular pathology codes. Use the appropriate molecular pathology procedure level code that includes the specific analyte listed after the code descriptor. If the analyte tested is not listed under one of the Tier 2 codes or is not represented by a Tier 1 code, use the unlisted molecular pathology procedure code, 81479."</p>
Professional Society	



Guidelines and Other Publications	
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CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

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