

Payment Policy 35

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 the event of a conflict, federal and state guidelines, as applicable, as well as the member's benefit plan document supersede the information in this policy. Additionally, to the extent there are any 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.

Overview

When molecular pathology tests are performed, there are CPT codes available to represent the specific tests performed. There are two groups of codes known as tier 1 and tier 2. Tier 1 codes represent only one gene or disease marker and are specific whereas tier 2 codes represent groups of possible conditions which are considered uncommon and rare compared to the conditions covered by tier 1 codes.

In keeping with payment integrity principles, the code of highest specificity and accuracy should be used to represent the test performed. In the cases of conditions represented by Tier 2 codes, disease specific precision is not possible so codes representing a group of conditions should be used.

BRCA1 and BRCA2 are commonly performed tests for breast, ovarian, fallopian tube, primary peritoneal, pancreatic, or prostate cancer.

If the diagnosis of the above cancers is/are present on a claim and BRCA1 and/or BRCA2 are being assessed, then the tier 1 CPT codes must be used, and Tier 2 codes would not be appropriate.

Additionally, if the above cancer diagnoses are present on a claim, an unlisted code (81479, 81599) should not be used.

Policy

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

Coverage is subject to the specific terms of the member's benefit plan.

Tier 1 code: Generally, describe testing for a specific gene or HLA locus associated with a specific disease

Tier 2 code: Represents 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. They are complexity based and each code can represent multiple rare conditions.

- If an ICD-10 of 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 also on the 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- <u>Supported ICD10 (combined diagnosis list from CMS)</u>
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

Code	Description- <u>Supported ICD10 (combined diagnosis list from CMS)</u>
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C54.1	Malignant neoplasm of endometrium
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C61	Malignant neoplasm of prostate
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast
Z15.04	Genetic susceptibility to malignant neoplasm of endometrium
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary
Z85.44	Personal history of malignant neoplasm of other female genital organs
Z85.46	Personal history of malignant neoplasm of prostate
Z85.89	Personal history of malignant neoplasm of other organs and systems
Z86.000	Personal history of in-situ neoplasm of 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)

Code	Code Description
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)

Documentation History

Type	Date	Action
Effective Date	11/5/2023	New Policy
Revised Date		

References

Government Agencies

Medicare Article A57355: Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing:
<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=57355>

Medicare Article A56199: Billing and Coding: Molecular Pathology Procedures
<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=56199>

LCD L35000:
<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35000>

Medicare [Article A58917: Billing and Coding: Molecular Pathology and Genetic Testing:](https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58917&bc=0)
<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58917&bc=0>

2021 CPT Book- Tier 2 Molecular Pathology Procedure Guidelines- Page 614

"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."

2022 CPT Book- Tier 2 Molecular Pathology Procedure Guidelines- Page 631

"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."

Professional Society Guidelines and Other Publications

Evicore-

https://www.evicore.com/-/media/files/evicore/clinical-guidelines/molad102a_molecular-pathology-tier-2-molecular-cpt-codes_v202021.pdf

"Tier 2 codes are intended to report a wide range of molecular pathology procedures for which Tier 1 or other test-specific CPT codes have not been assigned."

Other Reviewed Publications

State Medicaid

California Medicaid-

<https://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/pathmolec.pdf>

Does cover BRCA once in a lifetime but does not cover CPT 81400-8.

Washington Medicaid-

<https://www.hca.wa.gov/assets/billers-and-providers/Physician-related-serv-bg-20210701.pdf>

Page 350, CPT code 81479: Gene Expression profile (breast cancer) Breast Cancer Index
Breast cancer gene expression testing is covered when all of the following conditions are met:

- Stage 1 or 2 cancer
- The test result will help the patient make decisions about hormone therapy