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 plans 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

This policy outlines reimbursement guidelines for Breast Cancer Genetic Testing (Tier 1 vs Tier 2).

Reimbursement Guidelines

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.

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
Initial Creation 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
Revised Date	08/08/2025	Updated Template, references, and edited reimbursement guidelines

References

References This policy was developed using:

• CMS
• State Medicaid Regulatory Guidance
• State Contracts

Reference	Link
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
CMS	Article - Billing and Coding: BRCA1 and BRCA2 Genetic Testing (A56542)
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."

***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.*