BRCA1 and BRCA2 Genetic Testing

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➲ Terms and Conditions

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Policy Summary

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Overview

Specific patterns of breast and ovarian cancer are linked to the BRCA1 and BRCA2 genes, which cause hereditary breast and ovarian cancer syndrome HBOC. HBOC is an inherited cancer-susceptibility syndrome characterized by the following:

- Multiple HBOC related cancers within a family (i.e., invasive ductal carcinoma, ductal carcinoma in situ, epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, melanoma, prostate cancer with Gleason score =≥7, pancreatic cancer and melanoma);
- Cancers typically occur at an earlier age than in sporadic cases (i.e., cancers not associated with inherited genetic risk);
- Two or more primary cancers in a single individual. This could be multiple primary cancers of the same type (e.g., bilateral breast cancer) or primary cancers of different types related to HBOC (e.g., breast and ovarian);
- Cases of male breast cancer.

In addition, there are some histopathologic features that have been noted to occur more frequently in breast cancers that are associated with BRCA1 or BRCA2 mutations. Multiple studies have demonstrated that BRCA1 breast cancer is more likely to be characterized as estrogen receptor (ER) negative, progesterone receptor (PR) negative, and human epidermal growth factor receptor 2 (HER2) negative, also referred to as triple negative breast cancer. Studies indicate BRCA1 mutations are identified in 9% to 28% of patients with triple negative breast cancer.

Recently, germline genetic testing of BRCA1 and BRCA2 has been shown to be informative for treatment considerations in patients with ovarian cancer. Specifically, Lynparza® (olaparib), a poly ADP-ribose polymerase (PARP) inhibitor has been FDA-approved for use as monotherapy in patients with ovarian cancer and with deleterious or suspected deleterious germline BRCA1or BRCA2 mutation, who have been treated with three or more prior lines of chemotherapy.

BRCA1 and BRCA2 Testing Overview

The prevalence of BRCA mutations in the population is estimated between 1 in 300 and 1 in 800; however, specific mutations known as “founder mutations” occur more often in populations founded by a small ancestral group, including Ashkenazi (Eastern European) Jews, French Canadians, and Icelanders. The prevalence of BRCA mutations in the Ashkenazi Jewish population is approximately 1 in 40. Three recurrent BRCA1 and BRCA2 mutations have been identified in Ashkenazi Jewish individuals (i.e., a genetically distinct population of Jewish people of eastern and central European ancestry) and make up the vast majority of BRCA mutations that occur in this population.

For patients of Ashkenazi Jewish descent, initial testing is generally done for the three specific mutations that account for most hereditary breast and ovarian cancer in that population: 185delAG and 5382insC (also called 5385insC) in the BRCA1 gene and 6174delT in the BRCA2 gene. If the test results are negative, full analysis of the BRCA1 and BRCA2 genes is only considered if testing criteria for non-Jewish individuals are met.

Rearrangements, such as large genomic alterations including translocations, inversions, large deletions and insertions are believed to be responsible for 12% to 18% of BRCA1 inactivating mutations but are less common in BRCA2 and in individuals of Ashkenazi Jewish descent. The National Comprehensive Cancer Network (NCCN) guidelines note that comprehensive genetic testing includes full sequencing of BRCA1/BRCA2 and the detection of large genomic rearrangements. The NCCN recommends that since certain large genomic rearrangements are not detectable by a primary sequencing assay, additional testing may be needed in some cases.

Several national evidence-based and expert opinion guidelines and accrediting bodies recommend that genetic testing should be undertaken only in conjunction with independent pretest genetic counseling services in order to assist patients in complex clinical decision making. Post genetic testing counseling is also strongly recommended. The NCCN guidelines state that genetic counseling is a critical component of the cancer risk assessment process. In addition, the guidelines state that pre-test counseling should include a discussion of why the test is being offered and how test results may impact medical management, cancer risks associated with the genes being tested, the significance of possible test results for the individual and family, the likelihood of a positive result, technical aspects and accuracy of the test, and economic considerations. Per the guidelines, post-test counseling includes disclosure of results, discussion of the significance of the results for the individual and relevant family members, a discussion of the impact of the results on psychosocial aspects and on the medical management of the individual, and how and where the patient will receive follow-up care and access to additional resources.

Multi-Gene Panel Testing

Multigene panels for hereditary ovarian and breast cancer (HBOC) syndromes are available. In general, these panels test simultaneously for several genes associated with inherited breast and/or ovarian cancer, including but not limited to the BRCA1 and BRCA2 genes. The genes included, and the methods used in multigene panels vary by laboratory. Some cancer susceptibility testing panels include genes that have not been associated with hereditary breast or ovarian cancer and, in some cases, are not clinically actionable. Testing with a targeted panel may be indicated as a cost effective strategy when the individual’s symptoms or family history meet testing criteria for more than one hereditary cancer syndrome. All genes included in the test should be relevant to the personal and family history for the individual being tested.

Test Results and Management

A positive BRCA test result reveals the presence of a mutation in either the BRCA1 or BRCA2 gene that prevents the translation of the full-sized protein or that is known to interfere with protein function in other ways and is associated with increased cancer risks. Several strategies have been proposed for achieving the goal of reducing cancer risk for individuals with known BRCA mutations. The NCCN guidelines include detailed strategies and evidence review for at–risk patients.

A negative BRCA test result is interpreted within the context of a patient's individual and family cancer history, notably regarding whether any family member has previously been identified as carrying a mutation or not. An affected individual who has tested negative for a BRCA mutation may still have an inherited predisposing mutation in one of the BRCA genes that was not identified by testing, or a mutation in another gene that predisposes to breast or ovarian cancer. An individual in whom testing reveals they do not carry a BRCA1 or BRCA2 mutation that has been positively identified in another family member is considered to have a true negative result (i.e., they have not inherited the BRCA mutation nor associated increased cancer risks identified in other family members).

A person is considered to have an indeterminate result if that person is not a carrier of a known cancer-predisposing gene mutation and the carrier status of all other biologic family members is either also negative or unknown. Results are considered inconclusive if the individual is a carrier of an alteration that currently has no known clinical significance (variant of uncertain significance).

Guidelines

To be eligible for coverage, the individual being tested must have signs or symptoms of breast cancer (invasive or ductal carcinoma in situ (DCIS), ovarian cancer (including fallopian tube and primary peritoneal cancer), pancreatic cancer, or prostate cancer and meet one of the criteria below. Genetic testing for a known mutation in a family is a covered service for individuals with signs and/or symptoms of cancer. Testing of an unaffected individual or family member is not a covered benefit.

BRCA 1 and BRCA 2 testing consists of full sequence and duplication/deletion analysis. Genetic testing for a known mutation in a family may be limited to the known familial variant.

Criteria for Testing

Coverage is based upon the existing Local Coverage Determination (LCD) for the jurisdiction in which the procedure is performed.

- Individual with breast, ovarian, fallopian tube, primary peritoneal, pancreatic, or prostate cancer from a family with a known deleterious BRCA1 or BRCA2 gene mutation
- Individual with a personal history of ovarian, fallopian tube, or primary peritoneal cancer
- Individual with a breast cancer diagnosis meeting any of the following criteria:
  - Diagnosed ≤45 y
  - Triple negative breast cancer (estrogen receptor (ER) negative, progesterone receptor (PR) negative, and human epidermal growth factor receptor 2 (HER2) negative) breast cancer diagnosed ≤ 60 y
  - Diagnosed 46-50 y with:
    - An additional breast cancer primary
      Note: Two breast cancer primaries includes bilateral (contralateral) disease or two or more clearly separate ipsilateral primary tumors either synchronously or asynchronously.
    - ≥1 first, second, or third degree relative* with breast cancer at any age, or
    - ≥1 first, second, or third degree relative* with prostate cancer (Gleason score ≥7), or
    - An unknown or limited family history.
      Note: Medicare will cover BRCA-testing for an adopted individual with breast cancer diagnosed ≤50y that is suspicious of being a BRCA-related cancer. Individuals with limited family history/structure, defined as fewer than 2 female first-or second-degree relatives* having lived beyond age 45 in either lineage may also be eligible for BRCA gene testing. Similar to all testing, these situations require explanation of medical necessity for BRCA testing in the patient's medical record, and documentation of genetic counseling prior to BRCA testing.
  - Breast cancer diagnosed at any age, and
    - ≥1 first, second, or third degree relative* with breast cancer ≤50 y, or
    - ≥1 first, second, or third degree relative* with ovarian cancer at any age, or
    - ≥1 first, second, or third degree relative* with metastatic prostate cancer or pancreatic cancer at any age, or
    - ≥2 additional diagnoses of breast cancer at any age in patient and/or in close blood relatives*, or
    - A first, second, or third degree male relative* with breast cancer
    - For an individual of ethnicity associated with higher mutation frequency (e.g. Ashkenazi Jewish) no additional family history may be required.

    Note: Testing for Ashkenazi Jewish founder-specific mutations should be performed first. Comprehensive BRCA1/2 testing may be considered if ancestry also includes non-Ashkenazi Jewish relatives or if any of the other BRCA-related criteria are met.
  - Male breast cancer
- Personal history of prostate cancer (Gleason score ≥7) at any age with:
  - ≥1 first, second, or third degree relative* with ovarian cancer at any age, or
  - ≥1 first, second, or third degree relative* with breast cancer ≤50 y, or
  - ≥1 first, second, or third degree relative* with pancreatic cancer at any age, or
  - ≥1 first, second, or third degree relative* with metastatic prostate cancer pancreatic cancer at any age, or

- ≥2 first, second, or third degree relatives* with breast cancer and/or pancreatic cancer and/or prostate cancer (any grade) at any age, or
- Ashkenazi Jewish ancestry

- Personal history of pancreatic cancer at any age
- Personal history of metastatic prostate cancer (radiographic evidence of or biopsy-proven disease)
- BRCA1/2 pathogenic mutation detected by tumor profiling on any tumor type in the absence of germline mutation analysis

*The NCCN defines blood relative as first-(parents, siblings and children), second-(grandparents, aunts, uncles, nieces and nephews, grandchildren and half-siblings), and third degree-relatives (great-grandparents, great-aunts, great uncles, great grandchildren and first cousins) on same side of family.

Multi-Gene Panels

The indications and limitations of coverage listed in National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2) apply to genetic testing for susceptibility to breast or ovarian cancer. While Section 90.2 B describes specific coverage criteria for nationally covered tests, Section 90.2 D permits coverage of other NGS as a diagnostic laboratory test for patients with cancer when performed and ordered according to the requirements described by the NCD. As such, genetic testing for susceptibility to breast or ovarian cancer with multi-gene NGS panels (not otherwise covered under NCD 90.2 Section B) may be covered by this contractor as reasonable and necessary when ALL of the NCD criteria are met in addition to the following:

- All genes in the panel are relevant to the personal and family history for the individual being tested (panels with genes that are not relevant to the individual's personal and family history are not reasonable and necessary);
- Criteria listed under "Personal History of Female Breast Cancer" and/or "Personal History of Other Cancer" are met.
- Individual also meets criteria for at least ONE hereditary cancer syndrome for which NCCN guidelines provide clear testing criteria and management recommendations, including but not limited to HBOC, Li-Fraumeni Syndrome, Cowden Syndrome, or Lynch Syndrome.

While not required for payment, NCCN Guidelines recommend referral to a cancer genetics professional with expertise and experience in cancer genetics prior to genetic testing and after genetic testing. Examples of cancer genetics professionals with expertise and experience in cancer genetics include: an American Board of Medical Genetics or American Board of Genetic Counseling - certified or board eligible Clinical Geneticist, Medical Geneticist or Genetic Counselor not employed by a commercial genetic testing laboratory (excludes individuals employed by or contracted with a laboratory that is part of an Integrated Health System which routinely delivers health care services beyond just the laboratory test itself as these individuals are also considered independent); medical oncologist, obstetrician-gynecologist or other physician trained in medical cancer genetics, a genetic nurse credentialed as either a Genetic Clinical Nurse (GCN) or an Advanced Practice Nurse in Genetics (APGN) by either the Genetic Nursing Credentialing Commission (GNCC) or the American Nurses Credentialing Center (ANCC) who is not employed by a commercial genetic testing laboratory (excludes individuals employed by or contracted with a laboratory that is part of an Integrated Health System which routinely delivers health care services beyond just the laboratory test itself as these individuals are also considered independent).

Limitations

BRCA testing is limited to once-in-a-lifetime. If a patient has been previously tested for BRCA1 and BRCA2, repeat testing prior to Lynparza® (olaparib) therapy is not reasonable and necessary and will not be covered.

Nationally Non-Covered Indications

BRCA1/BRCA2 genetic testing is considered not reasonable and necessary, thus it is non-covered, for the following indications:

- Genetic screening in the general population. Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review. Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states " ...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury...". Furthermore, it has been longstanding CMS policy that "tests that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered unless explicitly authorized by statute".
- Testing of individuals with no personal history of breast, ovarian, fallopian tube, primary peritoneal, pancreatic, or prostate cancer. Such testing is considered screening and is excluded by Medicare statute.

- Testing of individuals under 18 years of age.

Documentation Requirements

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this policy guideline. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0136U	ATM (ataxia telangiectasia mutated) (e.g., ataxia telangiectasia) mRNA sequence analysis (List separately in addition to code for primary procedure)
0137U	PALB2 (partner and localizer of BRCA2) (e.g., 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) (e.g., hereditary breast and ovarian cancer) mRNA sequence analysis (List separately in addition to code for primary procedure)
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)
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

CPT Code	Description
Multi-Gene Panel	
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])
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])
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)
0131U	Hereditary breast cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (13 genes) (List separately in addition to code for primary procedure)
0132U	Hereditary ovarian cancer-related disorders (e.g., 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)
0133U	Hereditary prostate cancer-related disorders, targeted mRNA sequence analysis panel (11 genes) (List separately in addition to code for primary procedure)
0134U	Hereditary pan cancer (e.g., hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (18 genes) (List separately in addition to code for primary procedure)
0135U	Hereditary gynecological cancer (e.g., 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)
81432	Hereditary Breast Cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 10 genes, always including BRCA1, BRCA2, CDH1, MLH1, MSH2, MSH6, PALB2, PTEN, STK11, and TP53
81433	Hereditary Breast Cancer-related disorders (e.g., hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11

Non-Covered Diagnosis Code
Non-Covered Diagnosis Codes List This list contains diagnosis codes that are never covered when given as the primary reason for the test. If a code from this section is given as the reason for the test and you know or have reason to believe the service may not be covered, call UnitedHealthcare to issue an Integrated Denial Notice (IDN) to the member and you. The IDN informs the member of their liability for the non-covered service or item and appeal rights. You must make sure the member has received the IDN prior to rendering or referring for non-covered services or items in order to collect payment.

Definitions

BRCA-Related Cancers: Breast cancer, Ovarian cancer, pancreatic cancer or metastatic or high-risk (Gleason score >=7) prostate cancer

Founder Mutation: A Founder Mutation is a gene mutation observed with high frequency in a group that is or was geographically or culturally isolated, in which one or more of the ancestors was a carrier of the mutant gene.

Gleason Scoring: Gleason Scoring is a system of grading prostate cancer tissue based on how it looks under a microscope. Gleason Scores range from 2 to 10 and indicate how likely it is that a tumor will spread. A low Gleason Score means the cancer tissue is similar to normal prostate tissue and the tumor is less likely to spread. A high Gleason Score means the cancer tissue is very different from normal and the tumor is more likely to spread.

Multi-Gene Panel: Genetic tests that use next-generation sequencing to test multiple genes simultaneously. Also called multigene test, Multiple-Gene Panel test and multiple-gene test.

References

CMS National Coverage Determinations (NCDs)

NCD 90.2 Next Generation Sequencing (NGS)

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L36456 MolDX: BRCA1 and BRCA2 Genetic Testing	A56971 Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing	CGS	KY, OH	KY, OH
	A54689 Billing and Coding: MolDX: Myriad's BRACAnalysis CDx™			
L36499 BRCA1 and BRCA2 Genetic Testing	A57449 Billing and Coding: BRCA1 and BRCA2 Genetic Testing	First Coast	FL, PR, VI	FL, PR, VI
	A57968 BRCA1 and BRCA2 genetic testing revision to the Part A and Part B Billing and Coding Article			
	A57985 BRCA1 and BRCA2 genetic testing revision to the Part A and Part B Billing and Coding Article			
	A57438 BRCA1 and BRCA2 genetic testing revision to the Part A and Part B LCD			
L36715 BRCA1 and BRCA2 Genetic Testing	A56542 Billing and Coding: BRCA1 and BRCA2 Genetic Testing	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
L36161 MolDX: BRCA1 and BRCA2 Genetic Testing	A57354 Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
	A55294 Billing and Coding: MolDX: Myriad's BRACAnalysis CDx™			
L36163 MolDX: BRCA1 and BRCA2 Genetic Testing	A57355 Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
	A55295 Billing and Coding: MolDX: Myriad's BRACAnalysis CDx™			

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L36082 MolDX: BRCA1 and BRCA2 Genetic Testing	A56854 Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing A54338 Billing and Coding: MolDX: Myriad's BRACAnalysis CDx™	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36813 Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing	A57771 Billing and Coding: MolDX: BRCA1 and BRCA2 Genetic Testing A55224 Billing and Coding: MolDX: Myriad's BRACAnalysis CDx®	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
L34519 Molecular Pathology Procedures	A57451 Billing and Coding: Molecular Pathology Procedures	First Coast	FL, PR, VI	FL, PR, VI
L35000 Molecular Pathology Procedures	A56199 Billing and Coding: Molecular Pathology Procedures	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI, CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
L36021 MolDX: Molecular Diagnostic Tests (MDT)	A56973 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)	CGS	KY, OH	KY, OH
L35160 MolDX: Molecular Diagnostic Tests (MDT)	A57526 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L36256 MolDX: Molecular Diagnostic Tests (MDT)	A57527 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L35025 MolDX: Molecular Diagnostic Tests (MDT)	A56853 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L36807 MolDX: Molecular Diagnostic Tests (MDT)	A57772 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT)	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE

LCD	Article	Contractor	Medicare Part A	Medicare Part B
L38274 MolDX: Repeat Germline Testing	A57141 Billing and Coding: MolDX: Repeat Germline Testing	CGS	KY, OH	KY, OH
L38351 MolDX: Repeat Germline Testing	A57331 Billing and Coding: MolDX: Repeat Germline Testing	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L38353 MolDX: Repeat Germline Testing	A57332 Billing and Coding: MolDX: Repeat Germline Testing	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L38274 MolDX: Repeat Germline Testing	A58017 Billing and Coding: MolDX: Repeat Germline Testing	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
L38429 MolDX: Repeat Germline Testing	A57100 Billing and Coding: MolDX: Repeat Germline Testing	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE
N/A	A57910 Billing and Coding: MolDX: Testing of Multiple Genes	CGS	KY, OH	KY, OH
N/A	A58120 Billing and Coding: MolDX: Testing of Multiple Genes	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
N/A	A58121 Billing and Coding: MolDX: Testing of Multiple Genes	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
N/A	A57503 Billing and Coding: MolDX: Testing of Multiple Genes	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
N/A	A57880 Billing and Coding: MolDX: Testing of Multiple Genes	WPS	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY	IA, IN, KS, MI, MO, NE

CMS Benefit Policy Manual

Chapter 15; § 80.1-80.1.3 Clinical Laboratory Services

CMS Claims Processing Manual

Chapter 12; § 60 Payment for Pathology Services
Chapter 16, § 10.2 General Explanation of Payment; § 20 Calculation of Payment Rates-Clinical Laboratory Test Fee Schedules; § 40 Billing for Clinical Laboratory Tests

UnitedHealthcare Commercial Policy

Genetic Testing for Hereditary Cancer

Other(s)

CMS Clinical Laboratory Fee Schedule, CMS Website
Palmetto GBA MolDx Website
Tests Subject to CLIA Edits

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes

04/14/2021	**Policy Summary**
	Criteria for Testing
	• Added language to indicate coverage is based upon the existing Local Coverage Determination (LCD) for the jurisdiction in which the procedure is performed
	• Revised coverage criteria for individuals diagnosed at 46-50 years:
	  ○ Removed criterion requiring "greater than or equal to (≥) first, second, or third degree relative with pancreatic cancer at any age"
	  ○ Replaced "greater than or equal to (≥) first, second, or third degree relative with prostate cancer (Gleason score >7 *or metastatic*)" with "greater than or equal to (≥) first, second, or third degree relative with prostate cancer (Gleason score >7)"
	  ○ Replaced language indicating "*UnitedHealthcare* will cover BRCA-testing for an adopted individual with breast cancer diagnosed ≤ 50 years old (y) that is suspicious of being a BRCA-related cancer" with "*Medicare* will cover BRCA-testing for an adopted individual with breast cancer diagnosed ≤ 50 years old (y) that is suspicious of being a BRCA-related cancer"
	Multi-Gene Panels
	• Replaced language indicating "genetic testing for susceptibility to breast or ovarian cancer with multi-gene Next Generation Sequencing (NGS) panels (not otherwise covered under National Coverage Determination (NCD) 90.2 Section B) may be covered by *UnitedHealthcare*" with "genetic testing for susceptibility to breast or ovarian cancer with multi-gene NGS panels (not otherwise covered under NCD 90.2 Section B) may be covered by *this contractor*"
	• Revised coverage criteria; removed criterion requiring "pre-test genetic counseling by a cancer genetics professional has been performed and post-test genetic counseling by a cancer genetics professional meeting NCCN accreditation criterion is planned"
	Limitations
	• Added reference to "olaparib" with "Lynparza® (olaparib)"
	Applicable Codes
	• Added CPT codes 0136U, 0137U, and 0138U (previously listed as *Multi-Gene Panel* only)
	Supporting Information
	• Updated *References* section to reflect the most current information
	• Archived previous policy version MPG384.01

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.