

Genetic Testing for Hereditary Cancer

Guideline Number: MPG394.06

Approval Date: April 10, 2024

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Policy Summary

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Overview

An estimated 5-10% of cancers have a heritable component, and there are a growing number of hereditary cancer syndromes. Identifying pathogenic variants in genes associated with hereditary cancer syndromes can uncover genomic mechanisms that have predictive, diagnostic, and prognostic utility to patients and are used to better their management. Pathogenic variants in germline genes have been associated with an increased lifetime risk of hereditary breast and ovarian cancer (HBOC), colorectal cancer (CRC), as well as other cancers, such as endometrial, pancreatic, prostate, and melanoma. Traditionally, testing of genes associated with hereditary cancers was performed based on specific gene-disease relationships and an individual's personal or family history, often in a single-gene reflex fashion. However, the growing number of genes known to be associated with hereditary cancer syndromes and the overlap between clinical presentations has challenged this paradigm.

The application of Next Generation Sequencing (NGS) technology has facilitated multi-gene panel testing for definitive genes associated with many hereditary cancer syndromes. NGS has been shown to be more efficient than single-gene sequential testing and is becoming a routine component of the diagnostic process. For example, BRCA1 and BRCA2 (BRCA1/2) have historically been the most frequently tested genes in HBOC. Yet, it is now estimated that more than half of the individuals with hereditary breast cancer carry pathogenic variants in genes other than BRCA1/2. Breast cancer is also a component of several other hereditary cancer syndromes, such as Li-Fraumeni syndrome, Cowden syndrome, hereditary diffuse gastric cancer, and Peutz-Jeghers syndrome. Studies estimate that approximately 30% of all CRC cases are an inherited form of disease and nearly 5% are associated with highly penetrant hereditary clinical presentations. Lynch syndrome (LS), previously known as hereditary

non-polyposis colorectal cancer (HNPCC), is the most common hereditary CRC syndrome accounting for 2-3% of all CRC. It is caused by germline pathogenic variants in 5 mismatch repair genes, MHL1, MSH2, MSH6, EPCAM and PMS2. Traditionally, a testing cascade of microsatellite instability (MSI) analysis and/or immunohistochemistry was performed followed by testing of individual single genes. However, NGS allows for a majority of the genes to be tested simultaneously, reducing the time to diagnosis and reducing costs. The National Comprehensive Cancer Network (NCCN) guidelines have also expanded to incorporate testing of multiple genes into medical management recommendations.

Although inherited cancer syndromes each have their own clinical criteria for testing, there are some findings that are associated more frequently with hereditary cancers when compared to those that are acquired including: diagnosis at an earlier age than what is typically seen for that cancer type, 2 or more affected Close Blood Relatives (first-, second-, and third-degree relatives) on the same side of the family with the same type of cancer, multiple affected generations within 1 family. Additional findings include multiple cancer types occurring in the same individual, cancers that develop bilaterally, and presence of congenital conditions known to be associated with a particular cancer syndrome.

NGS is currently the most common methodology utilized for hereditary cancer gene testing. NGS is not a specific test, but a sequencing methodology utilized to capture genomic information. Unlike Sanger sequencing (the prior standard technology) that typically provides sequence information for a single DNA strand/molecule, NGS allows for massively parallel sequencing of millions of DNA molecules concurrently. This allows for capturing many relevant genomic targets simultaneously, usually by utilizing technologies, such as by polymerase chain reaction (PCR) amplification or hybrid capture. As such, NGS tests for use in germline cancer are often comprised of gene panels whose content is either relevant to a specific cancer type or condition, or a larger panel of genes that can be used for multiple cancer types.

Guidelines

If the test is an NGS test, it must abide by all conditions listed in NCD 90.2.

Contractors may determine coverage of Next Generation Sequencing (NGS) as a diagnostic laboratory test for patients with germline (inherited) cancer only when the test is performed in a CLIA-certified laboratory, when ordered by a treating physician, when results are provided to the treating physician for management of the patient and when the patient has:

- Any cancer diagnosis; and
- A clinical indication for germline (inherited) testing of hereditary cancers; and
- A risk factor for germline (inherited) cancer; and
- Not been previously tested with the same germline test using NGS for the same germline genetic content.

Contractors may determine coverage of diagnostic lab tests using NGS for RNA sequencing and protein analysis.

Nationally Non-Covered Indications

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".

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 |
|----------|--|
| 0101U | Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), 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 (15 genes [sequencing and deletion/duplication], EPCAM and GREM1 [deletion/duplication only]) |
| 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) |
| 0130U | Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), targeted mRNA sequence analysis panel (APC, CDH1, CHEK2, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, and TP53) (List separately in addition to code for primary procedure) |
| 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) |
| 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) |
| 0158U | MLH1 (mutL homolog 1) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure) |
| 0159U | MSH2 (mutS homolog 2) (e.g., hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure) |
| 0160U | MSH6 (mutS homolog 6) (e.g., hereditary colon cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure) |

| CPT Code | Description |
|----------|---|
| 0161U | PMS2 (PMS1 homolog 2, mismatch repair system component) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) mRNA sequence analysis (List separately in addition to code for primary procedure) |
| 0162U | Hereditary colon cancer (Lynch syndrome), targeted mRNA sequence analysis panel (MLH1, MSH2, MSH6, PMS2) (List separately in addition to code for primary procedure) |
| 0238U | Oncology (Lynch syndrome), genomic DNA sequence analysis of MLH1, MSH2, MSH6, PMS2, and EPCAM, including small sequence changes in exonic and intronic regions, deletions, duplications, mobile element insertions, and variants in non-uniquely mappable regions |
| 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) |
| 81201 | APC (adenomatous polyposis coli) (e.g., familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence |
| 81202 | APC (adenomatous polyposis coli) (e.g., familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; known familial variants |
| 81203 | APC (adenomatous polyposis coli) (e.g., familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; duplication/deletion variants |
| 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; full duplication/deletion analysis (i.e., detection of large gene rearrangements) |
| 81288 | MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis |
| 81292 | MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis |
| 81293 | MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants |
| 81294 | MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants |
| 81295 | MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis |
| 81296 | MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants |

| CPT Code | Description |
|----------|---|
| 81297 | MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants |
| 81298 | MSH6 (mutS homolog 6 [E. coli]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis |
| 81299 | MSH6 (mutS homolog 6 [E. coli]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants |
| 81300 | MSH6 (mutS homolog 6 [E. coli]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants |
| 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 |
| 81317 | PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis |
| 81318 | PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; known familial variants |
| 81319 | PMS2 (postmeiotic segregation increased 2 [S. cerevisiae]) (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; duplication/deletion variants |
| 81321 | PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis |
| 81322 | PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; known familial variant |
| 81323 | PTEN (phosphatase and tensin homolog) (e.g., Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant |
| 81351 | TP53 (tumor protein 53) (e.g., Li-Fraumeni syndrome) gene analysis; full gene sequence |
| 81352 | TP53 (tumor protein 53) (e.g., Li-Fraumeni syndrome) gene analysis; targeted sequence analysis (e.g., 4 oncology) |
| 81353 | TP53 (tumor protein 53) (e.g., Li-Fraumeni syndrome) gene analysis; known familial variant |
| 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 |
| 81435 | Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include sequencing of at least 10 genes, including APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11 |
| 81436 | Hereditary colon cancer disorders (e.g., Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); duplication/deletion analysis panel, must include analysis of at least 5 genes, including MLH1, MSH2, EPCAM, SMAD4, and STK11 |
| 81437 | Hereditary neuroendocrine tumor disorders (e.g., medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma); genomic sequence analysis panel, must include sequencing of at least 6 genes, including MAX, SDHB, SDHC, SDHD, TMEM127, and VHL |
| 81438 | Hereditary neuroendocrine tumor disorders (e.g., medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma); duplication/deletion analysis panel, must include analyses for SDHB, SDHC, SDHD, and VHL |

| CPT Code | Description |
|----------|---|
| 81441 | Inherited bone marrow failure syndromes (IBMFS) (e.g., Fanconi anemia, dyskeratosis congenita, Diamond-Blackfan anemia, Shwachman-Diamond syndrome, GATA2 deficiency syndrome, congenital amegakaryocytic thrombocytopenia) sequence analysis panel, must include sequencing of at least 30 genes, including BRCA2, BRIP1, DKC1, FANCA, FANCB, FANCC, FANCD2, FANCE, FANCF, FANCG, FANCI, FANCL, GATA1, GATA2, MPL, NHP2, NOP10, PALB2, RAD51C, RPL11, RPL35A, RPL5, RPS10, RPS19, RPS24, RPS26, RPS7, SBDS, TERT, and TINF2 (Effective 01/01/2023) |

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| Diagnosis Code | Description |
|---|--|
| For CPT Codes 81292, 81293 (Deleted 07/02/2022), and 81294 | |
| C16.0 | Malignant neoplasm of cardia |
| C16.1 | Malignant neoplasm of fundus of stomach |
| C16.2 | Malignant neoplasm of body of stomach |
| C16.3 | Malignant neoplasm of pyloric antrum |
| C16.4 | Malignant neoplasm of pylorus |
| C16.5 | Malignant neoplasm of lesser curvature of stomach, unspecified |
| C16.6 | Malignant neoplasm of greater curvature of stomach, unspecified |
| C16.8 | Malignant neoplasm of overlapping sites of stomach |
| C16.9 | Malignant neoplasm of stomach, unspecified |
| C17.0 | Malignant neoplasm of duodenum |
| C17.1 | Malignant neoplasm of jejunum |
| C17.2 | Malignant neoplasm of ileum |
| C17.3 | Meckel's diverticulum, malignant |
| C17.8 | Malignant neoplasm of overlapping sites of small intestine |
| C17.9 | Malignant neoplasm of small intestine, unspecified |
| C18.0 | Malignant neoplasm of cecum |
| C18.1 | Malignant neoplasm of appendix |
| C18.2 | Malignant neoplasm of ascending colon |
| C18.3 | Malignant neoplasm of hepatic flexure |
| C18.4 | Malignant neoplasm of transverse colon |
| C18.5 | Malignant neoplasm of splenic flexure |
| C18.6 | Malignant neoplasm of descending colon |
| C18.7 | Malignant neoplasm of sigmoid colon |
| C18.8 | Malignant neoplasm of overlapping sites of colon |
| C18.9 | Malignant neoplasm of colon, unspecified |
| C19 | Malignant neoplasm of rectosigmoid junction |
| C20 | Malignant neoplasm of rectum |
| C21.0 | Malignant neoplasm of anus, unspecified |
| C21.1 | Malignant neoplasm of anal canal |
| C21.2 | Malignant neoplasm of cloacogenic zone |
| C21.8 | Malignant neoplasm of overlapping sites of rectum, anus and anal canal |
| C22.0 | Liver cell carcinoma |
| C22.1 | Intrahepatic bile duct carcinoma |
| C22.2 | Hepatoblastoma |

| Diagnosis Code | Description |
|---|---|
| For CPT Codes 81292, 81293 (Deleted 07/02/2022), and 81294 | |
| C22.3 | Angiosarcoma of liver |
| C22.4 | Other sarcomas of liver |
| C22.7 | Other specified carcinomas of liver |
| C22.8 | Malignant neoplasm of liver, primary, unspecified as to type |
| C22.9 | Malignant neoplasm of liver, not specified as primary or secondary |
| C24.0 | Malignant neoplasm of extrahepatic bile duct |
| C24.9 | Malignant neoplasm of biliary tract, unspecified |
| 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 |
| 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 |
| C45.1 | Mesothelioma of peritoneum |
| C48.1 | Malignant neoplasm of specified parts of peritoneum |
| C48.2 | Malignant neoplasm of peritoneum, unspecified |
| C4.8 | Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum |
| C54.0 | Malignant neoplasm of isthmus uteri |
| C54.1 | Malignant neoplasm of endometrium |
| C54.2 | Malignant neoplasm of myometrium |
| C54.3 | Malignant neoplasm of fundus uteri |
| C54.8 | Malignant neoplasm of overlapping sites of corpus uteri |
| C54.9 | Malignant neoplasm of corpus uteri, unspecified |
| C55 | Malignant neoplasm of uterus, part unspecified |
| C56.1 | Malignant neoplasm of right ovary |
| C56.2 | Malignant neoplasm of left ovary |
| C56.3 | Malignant neoplasm of bilateral ovaries (Effective 10/01/2021) |
| 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 |
| C57.10 | Malignant neoplasm of unspecified broad ligament |
| C57.11 | Malignant neoplasm of right broad ligament |
| C57.12 | Malignant neoplasm of left broad ligament |
| C57.20 | Malignant neoplasm of unspecified round ligament |
| C57.21 | Malignant neoplasm of right round ligament |
| C57.22 | Malignant neoplasm of left round ligament |
| C57.3 | Malignant neoplasm of parametrium |
| C57.4 | Malignant neoplasm of uterine adnexa, unspecified |

| Diagnosis Code | Description |
|---|---|
| For CPT Codes 81292, 81293 (Deleted 07/02/2022), and 81294 | |
| C64.1 | Malignant neoplasm of right kidney, except renal pelvis |
| C64.2 | Malignant neoplasm of left kidney, except renal pelvis |
| C64.9 | Malignant neoplasm of unspecified kidney, except renal pelvis |
| C65.1 | Malignant neoplasm of right renal pelvis |
| C65.2 | Malignant neoplasm of left renal pelvis |
| C65.9 | Malignant neoplasm of unspecified renal pelvis |
| C66.1 | Malignant neoplasm of right ureter |
| C66.2 | Malignant neoplasm of left ureter |
| C66.9 | Malignant neoplasm of unspecified ureter |
| C68.0 | Malignant neoplasm of urethra |
| C68.1 | Malignant neoplasm of paraurethral glands |
| C68.8 | Malignant neoplasm of overlapping sites of urinary organs |
| C68.9 | Malignant neoplasm of urinary organ, unspecified |
| C71.0 | Malignant neoplasm of cerebrum, except lobes and ventricles |
| C71.1 | Malignant neoplasm of frontal lobe |
| C71.2 | Malignant neoplasm of temporal lobe |
| C71.3 | Malignant neoplasm of parietal lobe |
| C71.4 | Malignant neoplasm of occipital lobe |
| C71.5 | Malignant neoplasm of cerebral ventricle |
| C71.6 | Malignant neoplasm of cerebellum |
| C71.7 | Malignant neoplasm of brain stem |
| C71.8 | Malignant neoplasm of overlapping sites of brain |
| C71.9 | Malignant neoplasm of brain, unspecified |
| C78.5 | Secondary malignant neoplasm of large intestine and rectum (Deleted 08/20/2022) |
| D12.0 | Benign neoplasm of cecum |
| D12.1 | Benign neoplasm of appendix |
| D12.2 | Benign neoplasm of ascending colon |
| D12.3 | Benign neoplasm of transverse colon |
| D12.4 | Benign neoplasm of descending colon |
| D12.5 | Benign neoplasm of sigmoid colon |
| D12.6 | Benign neoplasm of colon, unspecified |
| K63.5 | Polyp of colon |
| L85.3 | Xerosis cutis |
| Z15.04 | Genetic susceptibility to malignant neoplasm of endometrium (Deleted 08/20/2022) |
| Z15.09 | Genetic susceptibility to other malignant neoplasm (Deleted 08/20/2022) |
| Z80.0 | Family history of malignant neoplasm of digestive organs (Deleted 08/20/2022) |
| Z85.00 | Personal history of malignant neoplasm of unspecified digestive organ |
| Z85.030 | Personal history of malignant carcinoid tumor of large intestine (Effective 01/01/2021) |
| Z85.038 | Personal history of other malignant neoplasm of large intestine |
| Z85.040 | Personal history of malignant carcinoid tumor of rectum (Effective 01/01/2021) |
| Z85.048 | Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus |

| Diagnosis Code | Description |
|---|---|
| For CPT Codes 81292, 81293 (Deleted 07/02/2022), and 81294 | |
| Z85.42 | Personal history of malignant neoplasm of other parts of uterus |
| Z85.43 | Personal history of malignant neoplasm of ovary |
| Z85.53 | Personal history of malignant neoplasm of renal pelvis |
| Z85.54 | Personal history of malignant neoplasm of ureter |
| Z85.59 | Personal history of malignant neoplasm of other urinary tract organ |
| Z85.841 | Personal history of malignant neoplasm of brain |
| Z86.010 | Personal history of colonic polyps |
| For CPT Codes 81321 and 81323 | |
| C45.1 | Mesothelioma of peritoneum |
| C48.1 | Malignant neoplasm of specified parts of peritoneum |
| C48.2 | Malignant neoplasm of peritoneum, unspecified |
| C48.8 | Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum |
| C54.0 | Malignant neoplasm of isthmus uteri |
| C54.1 | Malignant neoplasm of endometrium |
| C54.2 | Malignant neoplasm of myometrium |
| C54.3 | Malignant neoplasm of fundus uteri |
| C54.8 | Malignant neoplasm of overlapping sites of corpus uteri |
| C54.9 | Malignant neoplasm of corpus uteri, unspecified |
| C55 | Malignant neoplasm of uterus, part unspecified |
| C56.1 | Malignant neoplasm of right ovary |
| C56.2 | Malignant neoplasm of left ovary |
| C56.3 | Malignant neoplasm of bilateral ovaries (Effective 10/01/2021) |
| 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 |
| C57.10 | Malignant neoplasm of unspecified broad ligament |
| C57.11 | Malignant neoplasm of right broad ligament |
| C57.12 | Malignant neoplasm of left broad ligament |
| C57.20 | Malignant neoplasm of unspecified round ligament |
| C57.21 | Malignant neoplasm of right round ligament |
| C57.22 | Malignant neoplasm of left round ligament |
| C57.3 | Malignant neoplasm of parametrium |
| C57.4 | Malignant neoplasm of uterine adnexa, unspecified |
| C61 | Malignant neoplasm of prostate |
| C67.0 | Malignant neoplasm of trigone of bladder |
| C67.1 | Malignant neoplasm of dome of bladder |
| C67.2 | Malignant neoplasm of lateral wall of bladder |
| C67.3 | Malignant neoplasm of anterior wall of bladder |
| C67.4 | Malignant neoplasm of posterior wall of bladder |
| C67.5 | Malignant neoplasm of bladder neck |

| Diagnosis Code | Description |
|--------------------------------------|---|
| For CPT Codes 81321 and 81323 | |
| C67.6 | Malignant neoplasm of ureteric orifice |
| C67.7 | Malignant neoplasm of urachus |
| C67.8 | Malignant neoplasm of overlapping sites of bladder |
| C67.9 | Malignant neoplasm of bladder, unspecified |
| C71.0 | Malignant neoplasm of cerebrum, except lobes and ventricles |
| C71.1 | Malignant neoplasm of frontal lobe |
| C71.2 | Malignant neoplasm of temporal lobe |
| C71.3 | Malignant neoplasm of parietal lobe |
| C71.4 | Malignant neoplasm of occipital lobe |
| C71.5 | Malignant neoplasm of cerebral ventricle |
| C71.6 | Malignant neoplasm of cerebellum |
| C71.7 | Malignant neoplasm of brain stem |
| C71.8 | Malignant neoplasm of overlapping sites of brain |
| C71.9 | Malignant neoplasm of brain, unspecified |
| C7A.010 | Malignant carcinoid tumor of the duodenum |
| C7A.011 | Malignant carcinoid tumor of the jejunum |
| C7A.012 | Malignant carcinoid tumor of the ileum |
| C7A.019 | Malignant carcinoid tumor of the small intestine, unspecified portion |
| C7A.020 | Malignant carcinoid tumor of the appendix |
| C7A.021 | Malignant carcinoid tumor of the cecum |
| C7A.022 | Malignant carcinoid tumor of the ascending colon |
| C7A.023 | Malignant carcinoid tumor of the transverse colon |
| C7A.024 | Malignant carcinoid tumor of the descending colon |
| C7A.025 | Malignant carcinoid tumor of the sigmoid colon |
| C7A.026 | Malignant carcinoid tumor of the rectum |
| C7A.029 | Malignant carcinoid tumor of the large intestine, unspecified portion |
| C7A.090 | Malignant carcinoid tumor of the bronchus and lung |
| C7A.091 | Malignant carcinoid tumor of the thymus |
| C7A.092 | Malignant carcinoid tumor of the stomach |
| C7A.093 | Malignant carcinoid tumor of the kidney |
| C7A.094 | Malignant carcinoid tumor of the foregut, unspecified |
| C7A.095 | Malignant carcinoid tumor of the midgut, unspecified |
| C7A.096 | Malignant carcinoid tumor of the hindgut, unspecified |
| C7A.098 | Malignant carcinoid tumors of other sites |
| C7A.1 | Malignant poorly differentiated neuroendocrine tumors |
| C7A.8 | Other malignant neuroendocrine tumors |
| C7B.01 | Secondary carcinoid tumors of distant lymph nodes |
| C7B.02 | Secondary carcinoid tumors of liver |
| C7B.03 | Secondary carcinoid tumors of bone |
| C7B.04 | Secondary carcinoid tumors of peritoneum |
| C7B.09 | Secondary carcinoid tumors of other sites |

| Diagnosis Code | Description |
|--------------------------------------|--|
| For CPT Codes 81321 and 81323 | |
| C7B.1 | Secondary Merkel cell carcinoma |
| C7B.8 | Other secondary neuroendocrine tumors |
| D29.1 | Benign neoplasm of prostate |
| D3A.010 | Benign carcinoid tumor of the duodenum |
| D3A.011 | Benign carcinoid tumor of the jejunum |
| D3A.012 | Benign carcinoid tumor of the ileum |
| D3A.019 | Benign carcinoid tumor of the small intestine, unspecified portion |
| D3A.020 | Benign carcinoid tumor of the appendix |
| D3A.021 | Benign carcinoid tumor of the cecum |
| D3A.022 | Benign carcinoid tumor of the ascending colon |
| D3A.023 | Benign carcinoid tumor of the transverse colon |
| D3A.024 | Benign carcinoid tumor of the descending colon |
| D3A.025 | Benign carcinoid tumor of the sigmoid colon |
| D3A.026 | Benign carcinoid tumor of the rectum |
| D3A.029 | Benign carcinoid tumor of the large intestine, unspecified portion |
| D3A.090 | Benign carcinoid tumor of the bronchus and lung |
| D3A.091 | Benign carcinoid tumor of the thymus |
| D3A.092 | Benign carcinoid tumor of the stomach |
| D3A.093 | Benign carcinoid tumor of the kidney |
| D3A.094 | Benign carcinoid tumor of the foregut, unspecified |
| D3A.095 | Benign carcinoid tumor of the midgut, unspecified |
| D3A.096 | Benign carcinoid tumor of the hindgut, unspecified |
| D3A.098 | Benign carcinoid tumors of other sites |
| D3A.8 | Other benign neuroendocrine tumors |
| D40.0 | Neoplasm of uncertain behavior of prostate |
| N40.0 | Benign prostatic hyperplasia without lower urinary tract symptoms |
| N40.1 | Benign prostatic hyperplasia with lower urinary tract symptoms |
| N40.2 | Nodular prostate without lower urinary tract symptoms |
| N40.3 | Nodular prostate with lower urinary tract symptoms |
| N42.31 | Prostatic intraepithelial neoplasia |
| N42.32 | Atypical small acinar proliferation of prostate |
| N42.39 | Other dysplasia of prostate |
| N42.83 | Cyst of prostate |
| R31.1 | Benign essential microscopic hematuria |
| R31.29 | Other microscopic hematuria |
| For CPT Codes 81351 and 81352 | |
| C88.8 | Other malignant immunoproliferative diseases |
| C91.10 | Chronic lymphocytic leukemia of B-cell type not having achieved remission (Effective 08/01/2023) |
| C91.11 | Chronic lymphocytic leukemia of B-cell type in remission (Effective 08/01/2023) |
| C91.12 | Chronic lymphocytic leukemia of B-cell type in relapse (Effective 08/01/2023) |
| C92.00 | Acute myeloblastic leukemia, not having achieved remission |

| Diagnosis Code | Description |
|--------------------------------------|--|
| For CPT Codes 81351 and 81352 | |
| C92.01 | Acute myeloblastic leukemia, in remission |
| C92.02 | Acute myeloblastic leukemia, in relapse |
| C92.20 | Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission |
| C92.22 | Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse |
| C92.30 | Myeloid sarcoma, not having achieved remission |
| C92.32 | Myeloid sarcoma, in relapse |
| C92.40 | Acute promyelocytic leukemia, not having achieved remission |
| C92.41 | Acute promyelocytic leukemia, in remission |
| C92.42 | Acute promyelocytic leukemia, in relapse |
| C92.50 | Acute myelomonocytic leukemia, not having achieved remission |
| C92.51 | Acute myelomonocytic leukemia, in remission |
| C92.52 | Acute myelomonocytic leukemia, in relapse |
| C92.60 | Acute myeloid leukemia with 11q23-abnormality not having achieved remission |
| C92.61 | Acute myeloid leukemia with 11q23-abnormality in remission |
| C92.62 | Acute myeloid leukemia with 11q23-abnormality in relapse |
| C92.A0 | Acute myeloid leukemia with multilineage dysplasia, not having achieved remission |
| C92.A1 | Acute myeloid leukemia with multilineage dysplasia, in remission |
| C92.A2 | Acute myeloid leukemia with multilineage dysplasia, in relapse |
| C92.Z0 | Other myeloid leukemia not having achieved remission |
| C92.Z2 | Other myeloid leukemia, in relapse |
| C92.90 | Myeloid leukemia, unspecified, not having achieved remission |
| C92.92 | Myeloid leukemia, unspecified in relapse |
| C93.00 | Acute monoblastic/monocytic leukemia, not having achieved remission |
| C93.02 | Acute monoblastic/monocytic leukemia, in relapse |
| C93.10 | Chronic myelomonocytic leukemia not having achieved remission |
| C93.12 | Chronic myelomonocytic leukemia, in relapse |
| C93.Z0 | Other monocytic leukemia, not having achieved remission |
| C93.Z2 | Other monocytic leukemia, in relapse |
| C93.90 | Monocytic leukemia, unspecified, not having achieved remission |
| C93.92 | Monocytic leukemia, unspecified in relapse |
| C94.00 | Acute erythroid leukemia, not having achieved remission |
| C94.02 | Acute erythroid leukemia, in relapse |
| C94.40 | Acute panmyelosis with myelofibrosis not having achieved remission |
| C94.41 | Acute panmyelosis with myelofibrosis, in remission |
| C94.42 | Acute panmyelosis with myelofibrosis, in relapse |
| C94.6 | Myelodysplastic disease, not elsewhere classified |
| C94.80 | Other specified leukemias not having achieved remission |
| C94.82 | Other specified leukemias, in relapse |
| C95.00 | Acute leukemia of unspecified cell type not having achieved remission |
| C95.02 | Acute leukemia of unspecified cell type, in relapse |
| C95.10 | Chronic leukemia of unspecified cell type not having achieved remission |

| Diagnosis Code | Description |
|--------------------------------------|---|
| For CPT Codes 81351 and 81352 | |
| C95.12 | Chronic leukemia of unspecified cell type, in relapse |
| C95.90 | Leukemia, unspecified not having achieved remission |
| C95.92 | Leukemia, unspecified, in relapse |
| C96.Z | Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue |
| C96.9 | Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified |
| D45 | Polycythemia vera |
| D46.0 | Refractory anemia without ring sideroblasts, so stated |
| D46.1 | Refractory anemia with ring sideroblasts |
| D46.20 | Refractory anemia with excess of blasts, unspecified |
| D46.21 | Refractory anemia with excess of blasts 1 |
| D46.22 | Refractory anemia with excess of blasts 2 |
| D46.A | Refractory cytopenia with multilineage dysplasia |
| D46.B | Refractory cytopenia with multilineage dysplasia and ring sideroblasts |
| D46.C | Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality |
| D46.4 | Refractory anemia, unspecified |
| D46.Z | Other myelodysplastic syndromes |
| D46.9 | Myelodysplastic syndrome, unspecified |
| D47.1 | Chronic myeloproliferative disease |
| D47.3 | Essential (hemorrhagic) thrombocythemia |
| D47.4 | Osteomyelofibrosis |
| D47.Z9 | Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue |
| D47.9 | Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified |
| D61.818 | Other pancytopenia |
| D69.49 | Other primary thrombocytopenia |
| D69.6 | Thrombocytopenia, unspecified |
| D69.8 | Other specified hemorrhagic conditions |
| D69.9 | Hemorrhagic condition, unspecified |
| D70.8 | Other neutropenia |
| D70.9 | Neutropenia, unspecified |
| D72.810 | Lymphocytopenia |
| D72.818 | Other decreased white blood cell count |
| D72.819 | Decreased white blood cell count, unspecified |
| D72.821 | Monocytosis (symptomatic) |
| D72.828 | Other elevated white blood cell count |
| D72.829 | Elevated white blood cell count, unspecified |
| D72.89 | Other specified disorders of white blood cells |
| D72.9 | Disorder of white blood cells, unspecified |
| D75.81 | Myelofibrosis |
| D75.89 | Other specified diseases of blood and blood-forming organs |
| D75.9 | Disease of blood and blood-forming organs, unspecified |
| D77 | Other disorders of blood and blood-forming organs in diseases classified elsewhere |

| Diagnosis Code | Description |
|--------------------------------------|--|
| For CPT Codes 81351 and 81352 | |
| R16.1 | Splenomegaly, not elsewhere classified |
| R16.2 | Hepatomegaly with splenomegaly, not elsewhere classified |

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

Close Blood Relatives: Are defined as follows (NCCN, Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic 1.2023):

- First degree relatives include parents, siblings, and offspring.
- Second degree relatives include half-brothers/sisters, aunts/uncles, grandparents, grandchildren and nieces/nephews affected on the same side of the family.
- Third degree relatives include first cousins, great-aunts/uncles, great-grandchildren and great grandparents affected on same side of family.

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 |
|--|--|------------|--|--|
| Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer | | | | |
| L39017 MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer | A58734 Billing and Coding: MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer | CGS | KY, OH | KY, OH |
| L38972 MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer | A58679 Billing and Coding: MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer | Noridian | AS, CA, GU, HI, MP, NV | AS, CA, GU, HI, MP, NV |
| L38974 MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer | A58681 Billing and Coding: MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer | Noridian | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY |
| L38966 MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer | A58652 Billing and Coding: MoIDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer | Palmetto | AL, GA, NC, SC, TN, VA, WV | AL, GA, NC, SC, TN, VA, WV |

| LCD | Article | Contractor | Medicare Part A | Medicare Part B |
|--|--|------------|--|--|
| Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer | | | | |
| L39040 MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer | A58756 Billing and Coding: MolDX: Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer | WPS | IA, IN, KS, MI, MO, NE | IA, IN, KS, MI, MO, NE |
| | A55224 Billing and Coding: MolDX: Germline testing for use of PARP inhibitors | | | |
| Molecular Diagnostic Tests | | | | |
| L36021 MolDX: Molecular Diagnostic Tests (MDT) | A56973 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) | CGS | KY, OH | KY, OH |
| | A54689 Billing and Coding: Germline testing for use of PARP inhibitors | | | |
| | A54281 Billing and Coding: MolDX: TP53 Gene Test | | | |
| 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 |
| | A55294 Billing and Coding: MolDX: Germline testing for use of PARP inhibitors | | | |
| 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 |
| | A55295 Billing and Coding: MolDX: Germline testing for use of PARP inhibitors | | | |
| L35025 MolDX: Molecular Diagnostic Tests (MDT) | A56853 Billing and Coding: MolDX: Diagnostic Tests (MDT) | Palmetto | AL, GA, NC, SC, TN, VA, WV | AL, GA, NC, SC, TN, VA, WV |
| | A54338 Billing and Coding: MolDX: Germline testing for use of PARP inhibitors | | | |
| L36807 MolDX: Molecular Diagnostic Tests (MDT) | A57772 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) | WPS | IA, IN, KS, MI, MO, NE | IA, IN, KS, MI, MO, NE |
| | A55221 Billing and Coding: MolDX: TP53 Gene Test | | | |

| LCD | Article | Contractor | Medicare Part A | Medicare Part B |
|---|--|-------------|--|--|
| Molecular Pathology and Genetic Testing | | | | |
| L34519 Molecular Pathology Procedures | A57451 Billing and Coding: Molecular Pathology Procedures | First Coast | FL, PR, VI | FL, PR, VI |
| | A58918 Billing and Coding: Molecular Pathology and Genetic Testing | | | |
| | L36499 BRCA1 and BRCA2 Genetic Testing | | | |
| L34912 Genetic Testing for Lynch Syndrome | A57449 Billing and Coding: BRCA1 and BRCA2 Genetic Testing | | | |
| L34912 Genetic Testing for Lynch Syndrome | A57450 Billing and Coding: Genetic Testing for Lynch Syndrome | | | |
| 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 |
| L35062 Biomarkers Overview | A58917 Billing and Coding: Molecular Pathology and 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 |
| | A56541 Billing and Coding: Biomarkers Overview | | | |
| L35396 Biomarkers for Oncology | A52986 Billing and Coding: Biomarkers for Oncology | | | |
| L36715 BRCA1 and BRCA2 Genetic Testing | A56542 Billing and Coding: BRCA1 and BRCA2 Genetic Testing | | | |
| Repeat Germline Testing | | | | |
| L38288 MoIDX: Repeat Germline Testing | A57141 Billing and Coding: MoIDX: Repeat Germline Testing | CGS | KY, OH | KY, OH |
| L38351 MoIDX: Repeat Germline Testing | A57331 Billing and Coding: MoIDX: Repeat Germline Testing | Noridian | AS, CA, GU, HI, MP, NV | AS, CA, GU, HI, MP, NV |
| L38353 MoIDX: Repeat Germline Testing | A57332 Billing and Coding: MoIDX: 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 MoIDX: Repeat Germline Testing | A58017 Billing and Coding: MoIDX: Repeat Germline Testing | Palmetto | AL, GA, NC, SC, TN, VA, WV | AL, GA, NC, SC, TN, VA, WV |
| L38429 MoIDX: Repeat Germline Testing | A57100 Billing and Coding: MoIDX: Repeat Germline Testing | WPS | IA, IN, KS, MI, MO, NE | IA, IN, KS, MI, MO, NE |
| N/A | A53591 Billing and Coding: MoIDX: TP53 Gene Test | Palmetto | AL, GA, NC, SC, TN, VA, WV | AL, GA, NC, SC, TN, VA, WV |
| N/A | A55484 Billing and Coding: MoIDX: TP53 Gene Tests | Noridian | AS, CA, GU, HI, MP, NV | AS, CA, GU, HI, MP, NV |

| LCD | Article | Contractor | Medicare Part A | Medicare Part B |
|-----|---|------------|--|--|
| N/A | A55487 Billing and Coding: MolDX: TP53 Gene Tests | Noridian | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY |

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](#)

CMS Transmittal(s)

[Transmittal 12184, Change Request 13278, Dated 08/03/2023 \(International Classification of Diseases, 10th Revision \(ICD-10\) and Other Coding Revisions to National Coverage Determinations \(NCDs\)–January 2024 Update](#)

Other(s)

[CMS Clinical Laboratory Amendments \(CLIA\) Website](#)

[CMS Clinical Laboratory Fee Schedule, CMS Website](#)

[Palmetto GBA MolDx Website](#)

[Palmetto GBA MolDx Manual](#)

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 |
|------------|---|
| 04/10/2024 | <p>Applicable Codes</p> <p>Non-Covered Diagnosis Codes</p> <ul style="list-style-type: none"> Added Z02.84 <p>Administrative</p> <ul style="list-style-type: none"> Archived previous policy version MPG394.05 |

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 above 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.

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*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](#).