# *Genetic and Molecular Diagnostics – Testing for Cancer Diagnosis, Prognosis, and Treatment Selection*

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***IMPORTANT REMINDER***

*The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.*

*The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.*

*Some services or items may appear to be medically indicated for an individual but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.*

## DESCRIPTION

Genetic testing is testing performed to detect changes or variants in DNA, RNA, and/or chromosomes. Human Genome Variation Society (HGVS) nomenclature[1] is used to describe variants found in DNA and serves as an international standard. According to this nomenclature, the term "variant" is used to describe a change in a DNA or protein sequence, replacing previously used terms, such as "mutation." Pathogenic variants are variants associated with disease, while benign variants are not. The majority of genetic changes have unknown effects on human health, and these are referred to as variants of uncertain significance.

Genetic and biomarker testing is done for several purposes in patients with, or suspected of having cancer, including but not limited to: diagnostic and prognostic testing, or selecting appropriate treatments.

Some cancer-related tests may be eligible for Medicare coverage, while others are only eligible for coverage in select individuals or for certain conditions, and still others may not be eligible for coverage at all due to the nature of the Medicare program and the applicable requirements for reasonable and necessary services and diagnostic laboratory testing coverage.

*NOTE: See the "Policy Guidelines" below for important notes regarding Medicare and diagnostic laboratory and genetic testing services.*

## MEDICARE ADVANTAGE POLICY CRITERIA

**Note:** The tables in this policy provide information regarding a variety of topics. Examples include Medicare local carrier jurisdiction, specific genetic or molecular tests, as well as *types* or *categories* of tests.

I. See Table 2 to determine if a test is already addressed. This table contains a list of tests or types of tests with known Medicare coverage or non-coverage guidance. Some tests are never considered medically reasonable or necessary, while others have criteria which must be met for the genetic test to be covered.

   a. Note, the CPT and HCPCS codes included in the table are provided as a courtesy. Individual laboratories may choose to use different coding, and gene lists are subject to change.

   b. Some small panel tests may be reviewed by gene. If a panel test is not found in this Medicare Advantage Medical Policy, but all of the individual genes are addressed, the coverage decisions from the single gene policy for each individual gene may be applied if the applicable references are appropriate for the performing laboratory's service area.

II. If the test in question is not part of Table 2, see Table 1 for a state listing to determine if the laboratory is located in a geographical area that has adopted MolDX guidelines.

   a. For Medicare jurisdictions which **HAVE** adopted MolDX Program guidelines, additional research may be necessary for tests that are not included in Table 2. The MolDX Program requires that tests complete a technology assessment (TA) to determine if they may be covered.

   b. For Medicare jurisdictions which have **NOT** adopted MolDX Program guidelines, additional research may need to be performed to determine the applicable Medicare guideline for tests performed in a geographical area that has not adopted MolDX guidelines, when not included within Table 2.

### Table 1: MolDX Program and Medicare Jurisdictions

Back to Criteria

Medicare jurisdictions which have adopted the MolDX Program are indicated below (MolDX site). If

the performing laboratory is not located in one of the marked states, MolDX guidelines should not apply. Other Medicare guidance may be available.

| STATE | MolDX | STATE | MolDX | STATE | MolDX |
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| Alabama | X | Alaska | X | Arizona | X |
| Arkansas | | California | X | Colorado | |
| Connecticut | | Delaware | | Florida | |
| Georgia | X | Hawaii | X | Idaho | X |
| Illinois | | Indiana | X | Iowa | X |
| Kansas | X | Kentucky | X | Louisiana | |
| Maine | | Maryland | | Massachusetts | |
| Michigan | X | Minnesota | | Mississippi | |
| Missouri | X | Montana | X | Nebraska | X |
| Nevada | X | New Hampshire | | New Jersey | |
| New Mexico | | New York | | North Carolina | X |
| North Dakota | X | Ohio | X | Oklahoma | |
| Oregon | X | Pennsylvania | | Rhode Island | |
| South Carolina | X | South Dakota | X | Tennessee | X |
| Texas | | Utah | X | Vermont | |
| Virginia | X | Washington | X | West Virginia | X |
| Wisconsin | | Wyoming | | | |

| Table 2: Tests for Cancer Screening, Diagnosis, Prognosis, and Treatment | | |
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| **Note:** With few exceptions, Medicare does not cover screening tests in the absence of signs or symptoms of a disorder, and such testing is considered not medically necessary according to Title XVIII of the Social Security Act, Section 1862(a)(1)(A) where it 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…" (See also "Policy Guidelines" below). For all tests, please review the "Medicare Rationale/Reference" source carefully to determine whether criteria are met. | | |
| **TEST INFORMATION** | **MEDICARE RATIONALE / REFERENCE** | **Back to Criteria** |
| ***4kscore®*** *(81539)* Bio Reference Laboratories Inc. (NJ) | 4Kscore Test Algorithm (L37792) *(Applies to the indicated performing laboratory) (The companion article is A56653, which can be accessed directly from the LCD)*<br>If performed in other locations/states, see these additional references:<br>• MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L38985) *(Laboratories in NC, SC, AL, GA, TN, VA, WV)*<br>• MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39007) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)*<br>• MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39005) *(Laboratories in CA, NV)*<br>• Billing and Coding: Biomarker Testing for Prostate Cancer Diagnosis (A56609) *(Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT)*<br>• MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39042) *(Laboratories in IA, KS, MO, NE, IN, MI)*<br>• 4Kscore Test Algorithm (L37798) *(Laboratories in FL)*<br>• MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L38997) *(Laboratories in KY and OH)* | |
| ***Abbott RealTime IDH1, IDH2, Abbott Molecular*** *(81120, 81121)* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• Billing and Coding: MolDX: Abbott RealTime IDH1 and IDH2 testing for Acute Myeloid Leukemia (AML) (A55712)<br>*Laboratories in CA and NV:* | |

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| | • Billing and Coding: MolDX: Abbott RealTime IDH1 and IDH2 testing for Acute Myeloid Leukemia (AML) (A55711)<br><br>*NOTE: The above articles state: "This article reflects the FDA-approved indications on article creation date. MolDX will allow future FDA approved and amended indications for these tests." To view FDA-approved IDH1 and IDH2 tests and their corresponding medications, see the FDA List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools))* |
| ***Afirma™ GSC** (81546)* Veracyte® | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br><br>• MolDX: Molecular Testing for Risk Stratification of Thyroid Nodules (L39684). *The companion article A59511 can be accessed directly from the LCD.*<br><br>*Laboratories in CA and NV:*<br><br>• MolDX: Molecular Testing for Risk Stratification of Thyroid Nodules (L39682). *The companion article A59509 can be accessed directly from the LCD.*<br><br>The MolDX Program requires that tests complete a TA to provide evidence of analytical and clinical validity, and clinical utility. Reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review. The Afirma™ GSC (81546) has completed a TA and is considered "covered" when other LCD criteria are met.<br><br>*Laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA:*<br><br>• Biomarkers for Oncology (L35396) *(Use the guideline specific to Afirma™ found within the LCD. The companion article A52986, which provides coding and frequency allowance guidance, can be accessed directly from the LCD.)* |
| ***ALK Gene Tests*** | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br><br>• MolDX: Molecular Diagnostic Tests (MDT) (L36256) applies to genetic testing generally. *(Companion article A57527 can be accessed directly from the LCD.)*<br><br>*Laboratories in CA and NV:*<br><br>• MolDX: Molecular Diagnostic Tests (MDT) (L35160) applies to genetic testing generally. *(Companion article A57526 can be accessed directly from the LCD.)*<br><br>These LCDs requires that tests complete a technology assessment to determine if a test meets Medicare's reasonable and necessary requirement. Tests that have completed a TA are listed in the DEX™ Change Healthcare Registry website. In addition, **clinical documentation** |

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| | **must demonstrate how test results will be used** in the management or diagnosis of an illness or condition.<br><br>*Some FDA-approved medications are connected to companion diagnostics (CDx) tests for ALK rearrangements (see* List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). |
| ***BCR-ABL Gene Tests** (81206, 81207, 81208, 81479)*<br><br>***Note**: These references are for diagnostic testing. For BCR-ABL testing for treatment response or minimal residual disease, see entry below for "Minimal Residual Disease (MRD) Testing."* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br><br>• MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36186)<br>*The companion articles A55600 and A57422 can be accessed directly from the LCD.*<br><br>*Laboratories in CA and NV:*<br><br>• MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36180)<br>*The companion articles A55595 and A57421 can be accessed directly from the LCD.*<br><br>*Laboratories in AL, GA, TN, SC, VA, WV, NC:*<br><br>• MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36044)<br>*The companion article A56959, can be accessed directly from the LCD.*<br><br>**For all LCDs:** If a treating physician suspects a patient has myeloproliferative neoplasms (MPN) or myelodysplastic syndromes (MDS), it would be clinically appropriate to test BCR-ABL. This gene is considered "step one" in the LCDs and would be considered medically necessary for these and related indications, as outlined in the LCDs.<br><br>For BCR-ABL1 major and minor breakpoint fusion transcripts by the University of Iowa, reported with PLA code 0016U, apply the same BCR-ABL criteria used for 81206-81208 in the Wisconsin LCD for *MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease* (L36815).<br><br>For testing performed by BCR-ABL1 major and minor breakpoint fusion transcripts testing by Asuragen in Texas (also 0016U), see Novitas article (A52986) *(Documentation must clearly state how test results are actionable, and how they will promptly and directly be used for treatment decisions or diagnosis.)* |
| ***BCR-ABL Negative Myeloproliferative Disease testing** (includes JAK2, CALR, MPL gene testing) (81479)* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br><br>• MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36186)<br><br>*Laboratories in CA and NV:*<br><br>• MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36180) |

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| | *Laboratories in AL, GA, TN, SC, VA, WV, NC:*<br>• MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36044) *The companion article A56959 can be accessed directly from the LCD.*<br>*Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT:*<br>• See specific genes listed in Molecular Pathology Procedures (L35000)<br>*Laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA:*<br>• Biomarkers for Oncology (L35396)<br>**For MolDX LCDs:**<br>**Stepwise, single-gene (non-NGS) testing**: According to the LCDs, coverage for stepwise testing for *JAK2, CALR, and/or MPL* variants requires an initial negative result for *BCR-ABL* testing. Stepwise testing for these genes in the absence of prior *BCR-ABL* testing is therefore considered **not medically necessary** for Medicare.<br>**Non-stepwise testing**: "Molecular testing for BCR-ABL, JAK2, JAK, exon 12, and CALR/MPL genes by NGS is covered as medically necessary for the identification of myeloproliferative disorders."<br>***BCR-ABL* testing:** For patients suspected of having a myeloproliferative neoplasm (MPN) or myelodysplastic syndrome (MDS), *BCR-ABL* testing is usually performed as a first step. No specific criteria are provided in the LCDs for *BCR-ABL* testing, as it is considered the initial step of testing and may be considered **medically necessary**.<br>***JAK2* testing**: Stepwise testing for *JAK2* variants in these LCDs includes *JAK2V617F* [81270] and other *JAK2* targeted variant testing (e.g., exon 12) [81279]. Additional, separate reimbursement for other *JAK2* variant testing (e.g., exons 15-16) is not covered. |
| ***BDX-XL2 (Xpresys Lung® and Xpresys Lung 2®)*** *(81599, 0080U)*<br>Biodesix (previously Integrated Diagnostics) | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• BDX-XL2 (L37062) *Companion article A5735 can be accessed directly from the LCD. Coverage outlined in this LCD is limited to only XL2.*<br>*Laboratory in KS:*<br>• BDX-XL2 (L37216). *Companion article A57558 can be accessed directly from the LCD.* |

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| | • *The clinical utility for the earlier version of Xpresys Lung® is not noted as demonstrated in the same way XL2 has been demonstrated and is therefore considered* ***not medically necessary****.* |
| ***BluePrint®*** *(81479)* Agendia (CA) | MolDX: BluePrint® Billing and Coding (A55115) *(Applies to the indicated performing laboratory)* |
| ***Bladder Tumor Marker*** *(e.g., UroVysion, with or without FISH technology) (0465U, 0549U, 86294, 86316, 86386, 88120, 88121)* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• Bladder/Urothelial Tumor Markers (L36680). *Companion article A55029 can be accessed directly from the LCD.*<br>*Laboratories in CA and NV:*<br>• Bladder/Urothelial Tumor Markers (L36678). *Companion article A55028 can be accessed directly from the LCD.*<br>*Laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA:*<br>• Genetic Testing in Oncology: Specific Tests (L39365) |
| ***BRAF Gene Tests*** | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• Billing and Coding: MolDX: FDA-Approved BRAF Tests (A54420)<br>*Laboratories in CA and NV:*<br>• Billing and Coding: MolDX: FDA-Approved BRAF Tests (A54418)<br>*NOTE: The articles above state: "*This article reflects the FDA-approved indications on article creation date. MolDX will allow future FDA approved and amended indications for these tests.*" To view FDA-approved BRAF tests and their corresponding medications, see the FDA* List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) |
| ***BRCA1 and BRCA2 Testing for Treatment Selection*** *(Includes BRACAnalysis CDx and other panels limited to BRCA1 and BRCA2.*<br>***Note: This guidance applies only to testing to guide treatment selection*** *(i.e., Lynparza, Talzenna, Rubraca). For* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• Billing and Coding: MolDX: Germline testing for use of PARP inhibitors (A55295)<br>*Laboratories in CA or NV:*<br>• Billing and Coding: MolDX: Germline testing for use of PARP inhibitors (A55294)<br>*Laboratories in FL:* |

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| *testing for inherited cancer risk, see Cross References)* | • BRCA1 and BRCA2 Genetic Testing (L36499) *(Laboratories in FL)* |
| ***Breast Cancer Index℠*** *(aka BCI) (81518)* bioTheranostics, Inc. (CA) | • MolDX: Breast Cancer Index™ (BCI) Gene Expression Test (L37822) |
| ***CancerTypeID®*** *(81479 or 81540)* bioTheranostics, Inc. (CA) | • MolDX: bioTheranostics Cancer TYPE ID® Billing and Coding Guidelines (A54386) *(Applies to the indicated performing laboratory). Companion LCD L35160 can be accessed directly from the article.* |
| ***clonoSEQ®*** *(0364U, 81479)* Adaptive Biotechnologies | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, UT, WY:*<br>• MolDX: Minimal Residual Disease Testing for Cancer (L38816).<br>This LCD states "For patients with or without cancer (as defined above), established standard-of-care MRD tests using single-gene PCR (i.e., BCR-ABL1) are covered under this policy according to testing schedules outlined in national (i.e., NCCN) or society guidelines." *Companion article A58997 can be accessed directly from the LCD.* |
| ***Colorectal Screening Tests*** *(CPT coding varies)*<br><br>*Examples:*<br>• BeScreened-CRC (0163U) (Beacon Biomedical and Sonora Quest Laboratory)<br>• Cologuard™ Colorectal Screening (81528) Exact Sciences Laboratories<br>• Cologuard Plus™ (0464U) Exact Sciences Laboratories (*see adjacent Note addressing this test*)<br>• ColoSense (0421U) Geneoscopy<br>• Colonsentry® (81479) Innovative Diagnostic Laboratory (VA)<br>• Epi proColon (G0327)<br>• FirstSight$^{CRC}$ (0091U) (CA)<br>• Guardant Shield (0537U) (CA) | **NCD for Colorectal Cancer Screening Tests** (210.3)<br>Medicare benefits for colorectal cancer (CRC) screening tests are limited to tests found in this NCD and **not all tests are eligible for coverage under this NCD**. Some DNA tests are blood-based (e.g., Epi proColon), and others are stool-based tests (e.g., Cologuard™).<br>See Medicare Preventive Services: Colorectal Cancer Screening for additional information and coding.<br>Coverage of blood-based biomarker screening tests requires FDA approval or marketing clearance. Tests such as the BeScreened-CRC and ColonSentry® that do not have this clearance are **not covered**. In addition, tests must meet performance characteristic thresholds. The Epi proColon is an FDA-cleared blood-based test, but according to the Decision Memo for Screening for Colorectal Cancer - Blood-Based Biomarker Tests (CAG-00454N), this test does not meet the Medicare criteria for an appropriate blood-based biomarker CRC screening test, as it does not meet test performance characteristic requirements and thus, is not covered. |

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| • PolypDX™ (0002U) | |
| ***Colvera*** *(0229U)* Colvera Lab (NJ) | Genetic Testing in Oncology: Specific Tests (L39365) |
| ***COMPASS® Bone Marrow Evaluation*** *(81479)* Neogenomics/Genoptix (CA) | This test is not listed in the DEX™ Change Healthcare Registry website, indicating a TA has not been completed. The clinical utility of several gene components in this panel has not been demonstrated, and many of the individual gene components of this test have been reviewed by MolDX and determined not to meet Medicare's requirements for coverage. Therefore, this test is considered **not medically reasonable or necessary** according to the Palmetto GBA MolDX Program and the Social Security Act, §1862(a)(1)(A). |
| ***ConfirmMDx™*** *(81551)* MDxHealth (CA) | MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39005). *(The companion article A58718 can be accessed directly from the LCD).*<br><br>**Note:** This LCD/article combo also addresses Progensa PCA3 testing (CPT 81313) with versions for all MolDX areas. |
| ***Decipher Bladder TURBT®*** *(0016M)* Decipher Biosciences (CA) | MolDX: Molecular Diagnostic Tests (MDT) (L35160). According to the DEX™ Change Healthcare Registry website, this test is listed as a potentially covered test by MolDX for Medicare. |
| ***Decipher® Prostate Cancer Classifier Assay*** *(Decipher Biopsy and Decipher Post-Op) (81542, 81479)* GenomeDX or Decipher Biosciences (CA) | For localized prostate cancer:<br>• MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease (L38339) *The companion article A57372 can be accessed directly from the LCD.*<br>For castration-resistant and metastatic prostate cancer:<br>• MolDX: Gene Expression Profile Tests for Decision-Making in Castration Resistant and Metastatic Prostate Cancers (L39686). *The companion article A59513 can be accessed directly from the LCD.*<br>*The Decipher Biopsy and the Decipher Post-Op are both marketed under the name* Decipher® Prostate Cancer Classifier Assay*. Thus, the LCD applies to both versions.* |
| ***Decision DX Tests***, Castle Biosciences Inc. (AZ) | For ***DecisionDx-Melanoma*** *(81599):*<br>• MolDX: Melanoma Risk Stratification Molecular Testing (L37748). *(The companion article A57290 can be accessed directly from the LCD).* The DecisionDx-Melanoma |

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| | assay has completed a TA and is listed in the DEX™ Change Healthcare Registry website as "covered."<br><br>For ***DecisionDx DiffDx-Melanoma*** *(0314U):*<br><br>• MolDX: Melanoma Risk Stratification Molecular Testing (L37748). *(The companion article A57290 can be accessed directly from the LCD).* The DecisionDx DiffDx-Melanoma assay has completed a TA and is listed in the DEX™ Change Healthcare Registry website as "covered."<br><br>For ***DecisionDx-SCC*** *(0315U):*<br><br>• MolDX: Molecular Biomarker Testing for Risk Stratification of Cutaneous Squamous Cell Carcinoma (L39589)<br><br>For ***DecisionDx-UM (uveal melanoma)*** *(81552, 84999, 0081U)*:<br><br>• MolDX: DecisionDx-UM (Uveal Melanoma) (L37072) |
| ***RiskReveal***™ *(previously DetermaRx™) (0288U)* Razor Genomics (CA) | MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer (L38327). *(Applies to the indicated performing laboratory) (Companion article A57329 can be accessed directly from the LCD.* |
| ***EGFR Gene Tests*** *(81235)* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br><br>• Billing and Coding: MolDX: FDA-Approved EGFR Tests (A54424)<br><br>*Laboratories in CA and NV:*<br><br>• Billing and Coding: MolDX: FDA-Approved EGFR Tests (A54422)<br><br>*The above guideline for EGFR tests states: "This article reflects the FDA-approved indications on article creation date. MolDX will allow future FDA approved and amended indications for these tests." To view FDA-approved EGFR tests and their corresponding medications, see the FDA* List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)*)* |
| ***EndoPredict® Breast Cancer Gene Expression Test*** *(81599, 81518, 81522)* Myriad Genetics (UT) | MolDX: EndoPredict® Breast Cancer Gene Expression Test (L37311) *(Applies to the indicated performing laboratory) (Companion article A57608 can be accessed directly from the LCD.)* |

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| ***Envisage*** *(0386U)* and ***Esopredict*** *(0398U)* Capsulomics/Previse (MD) | Biomarkers for Oncology (L35396) *(Applies to the indicated performing laboratory)* |
| ***ExoDx™ Prostate*** *(0005U)* Exosome Diagnostics (MA) | Billing and Coding: Biomarker Testing for Prostate Cancer Diagnosis (A56609) *(Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT)* |
| ***FGFR3 Gene Tests for Bladder Cancer*** *(coding varies)* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer (L38649). *Companion article can be accessed directly from the LCD.*<br>*Laboratories in CA and NV:*<br>• MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer (L38647). *Companion article can be accessed directly from the LCD.*<br>*Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT:*<br>• Molecular Pathology Procedures (L35000). *See the guideline specific to the gene within the LCD and also article A56199, which can be accessed directly from the LCD. Before applying non-coverage, see the "Note" below for FGFR3 testing.*<br>*Laboratories in CO, NM, OK, TX, AK, LA, MS, DE, MD, PA, NJ:*<br>• Biomarkers for Oncology (L35396)<br>***NOTE****: FDA-approved companion diagnostic tests (e.g., therascreen® FGFR RGQ PCR Kit) may be allowed for the indication(s) noted on the FDA approval list (see the FDA List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools).* |
| ***FISH*** *(fluorescent in situ hybridization)* **for myelodysplastic syndromes** *(88271, 88273, 88274, 88275, 88291)* | MolDX: MDS FISH (L37602) *Per the LCD, "Molecular NGS testing alone (for myeloid mutations) or in combination with FISH testing is not reasonable and necessary for the diagnosis of MDS, and is not a Medicare benefit." Companion article A56913 can be directly accessed from the LCD.* |
| ***FLT3 Gene Tests*** *(coding varies)* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• MolDX: Molecular Diagnostic Tests (MDT) L36256 applies to genetic testing generally. *Companion article A57527 can be accessed directly from the LCD.*<br>*Laboratories in CA and NV:* |

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| | • MolDX: Molecular Diagnostic Tests (MDT) L35160 applies to genetic testing generally. *Companion article A57526 can be accessed directly from the LCD.*<br><br>These LCDs requires that tests complete a technology assessment to determine if a test meets Medicare's reasonable and necessary requirement. Tests that have completed a MolDX technology assessment are listed in the DEX™ Change Healthcare Registry website. In addition, **clinical documentation must demonstrate how test results will be used** in the management or diagnosis of an illness or condition.<br><br>*NOTE: Coverage may also be allowed for FDA approved and amended indications for these tests. To view FDA-approved FLT3 tests and their corresponding medications, see the FDA* List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools). |
| ***FoundationOne® Heme*** *(405 genes) (81479)* Foundation Medicine, Inc. (MA or NC) | According to the DEX™ Change Healthcare Registry website, the FoundationOne® Heme test is listed as a **potentially covered** test by MolDX for Medicare (listed as FoundationOne® Heme-Hematologic Malignancies and Sarcomas; Test ID: Test_5684).<br><br>For myeloid malignancies (including suspected malignancies):<br><br>• MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38047) *(Use for laboratories in either NC or MA)*<br><br>For sarcoma or other solid tumor testing using blood samples:<br><br>• MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L38043) *(Use for laboratories in either NC or MA)*<br><br>For sarcoma or other solid tumor testing using tumor samples:<br><br>• MolDX: Next-Generation Sequencing for Solid Tumors (L38045) *(Use for laboratories in either NC or MA)* |
| ***GeneTrails® Heme Fusion Gene Panel*** *(81456, 81479)* OHSU Knight Diagnostics Laboratories (OR) | • MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38125). *This test is listed in the DEX™ Change Healthcare Registry as "not covered" and is therefore considered* ***not medically reasonable and necessary****.* |
| ***GeneTrails® Comprehensive Solid Tumor Panel*** *(124 genes) (81445, 81479) and* | • MolDX: Next-Generation Sequencing for Solid Tumors (L38121). *Companion article A57905 can be accessed directly from the LCD. These tests have completed a TA and are listed in the DEX™ Change Healthcare Registry as "covered."* |

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| ***GeneTrails® Solid Tumor Fusion Gene Panel*** *(20 genes) (81445, 81479)* OHSU Knight Diagnostics Laboratories (OR) | |
| ***Guardant360®*** *(739 genes) (0326U)* Guardant Health (CA)<br><br>***Note:*** *For the* ***Guardant360® CDx*** *test, see the row for "Next Generation Sequencing Panel Tests Subject to the Medicare NCD 90.2" below.* | • MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L39230). *Companion article A57867 can be accessed directly from the LCD.*<br><br>*The Guardant360® 739-gene panel has completed a TA and is listed in the DEX™ Change Healthcare Registry as "covered".*<br><br>*The Guardant360® LDT is not currently found in the DEX™ Change Healthcare Registry website, indicating a TA has not yet been completed. Therefore, this test is considered* ***not medically reasonable and necessary*** |
| ***Guardant360 Response™*** *(0422U, 81479) and* ***Guardant Reveal™*** *(0569U)* Guardant Health (CA) | MolDX: Minimal Residual Disease Testing for Cancer (L38814). *Companion article A58456 can be accessed directly from the LCD and lists the specific coverage of these tests* |
| ***HER2 (ERBB2) Testing*** *(includes DEPArrayTM HER2, CellSearch® HER2 Circulating Tumor Cell) (0009U, 0338U, 81479))* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br><br>• MolDX: Molecular Diagnostic Tests (MDT) (L36256) *Companion article A57527 can be accessed directly from the LCD.)*<br><br>*Laboratories in CA and NV:*<br><br>• MolDX: Molecular Diagnostic Tests (MDT) (L35160) *Companion article A57526 can be accessed directly from the LCD.*<br><br>These LCDs requires that tests complete a technology assessment to determine if a test meets Medicare's reasonable and necessary requirement. Tests that have completed a MolDX technology assessment are listed in the DEX™ Change Healthcare Registry. In addition, **clinical documentation must demonstrate how test results will be used** in the management or diagnosis of an illness or condition.<br><br>*Laboratories in CO, NM, OK, TX, AK, LA, MS, DE, MD, PA, NJ*<br><br>• Biomarkers for Oncology (L35396) |
| ***IDH1/IDH2 Gene Tests*** *(81120, 81121)* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:* |

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| *See entry for "Abbott RealTime IDH2" testing above for that test.* | • MolDX: Molecular Diagnostic Tests (MDT) (L36256) *Companion article A57527 can be accessed directly from the LCD.*<br><br>*Laboratories in CA and NV:*<br><br>• MolDX: Molecular Diagnostic Tests (MDT) (L35160) *Companion article A57526 can be accessed directly from the LCD.*<br><br>These LCDs requires that tests complete a technology assessment to determine if a test meets Medicare's reasonable and necessary requirement. Tests that have completed a MolDX technology assessment are listed in the DEX™ Change Healthcare Registry. In addition, **clinical documentation must demonstrate how test results will be used** in the management or diagnosis of an illness or condition. |
| ***Immunoscore*** *(0261U)* HalioDx or Veracyte (VA) | MolDX: The Palmetto LCD L35025 states reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review. This test is not currently found in the DEX™ Change Healthcare Registry, indicating a TA has not yet been completed. Therefore, this test is considered **not medically reasonable or necessary** according to the Palmetto GBA MolDX Program and the Social Security Act, §1862(a)(1)(A). |
| ***InvisionFirst™ - Lung*** *(aka InVision) (0388U, 81479)* Inivata (NC) | MolDX: Inivata, InVisionFirst, Liquid Biopsy for Patients with Lung Cancer (L37870) *Companion article A56924 can be accessed directly from the LCD.* |
| ***IsoPSA®*** *(0359U) Cleveland Diagnostics (OH)* | The CGS Administrators LCD Prostate Cancer Detection with IsoPSA® L39284 applies to this test. *(Companion article A59066 can be accessed directly from the LCD.)* |
| ***KRAS Gene Tests*** *(81275)* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br><br>• MolDX: FDA-Approved KRAS Tests (A54500). *Companion LCD L36256 can be accessed directly from the article.*<br><br>*Laboratories in CA and NV:*<br><br>• MolDX: FDA-Approved KRAS Tests (A54498). *Companion LCD L35160 can be accessed directly from the article.*<br><br>*NOTE: This guidance states: "This article reflects the FDA-approved indications on article creation date. MolDX will allow future FDA approved and amended indications for these tests." To view FDA-approved KRAS tests and their corresponding medications, see the FDA List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools).* |

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| ***LiquidHALLMARK®*** *(0530U, 0571U)* Lucence Health (CA) | MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L39230). *Companion article A58973 can be accessed directly from the LCD.* |
| ***LungLB®*** *(0317U)* LungLife AI® (CA) | MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells (L38643). This test is not currently found in the DEX™ Change Healthcare Registry, indicating a TA has not yet been completed. Therefore, this test is considered **not medically reasonable or necessary**. |
| ***Lymph2Cx*** *(0017M) and* ***Lymph3Cx Lymphoma Molecular Subtyping Assay*** *(0120U)* Mayo Clinic Laboratory (AZ, MN, FL) | *Laboratory in Arizona:*<br>• The MolDX Program requires labs to submit a technology assessment (TA) to provide evidence of analytical and clinical validity (AV/CV), and clinical utility (CU). *(Noridian article A54554)*<br>• These tests are listed in the DEX™ Change Healthcare Registry as "not covered." Therefore, they are considered **not medically reasonable and necessary** under Social Security Act §1862(a)(1)(A).<br>*Laboratory in Minnesota:*<br>• According to the LCD for *Molecular Pathology Procedures* (L35000), gene expression profiling for certain cancers is listed as a type of test that may not be covered.<br>*Laboratory in Florida:*<br>• The LCD for *Molecular Pathology Procedures* (L34519) includes the same note as that mentioned above. |
| ***MammaPrint®*** *(81521)* Agendia (CA) | MolDX: MammaPrint Billing and Coding Guidelines (A54445) |
| ***MGMT Gene Promoter Tests*** *(81287)* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• MolDX: MGMT Promoter Methylation Analysis (L36192). *Companion article A57433 can be accessed directly from the LCD.*<br>*Laboratories in CA and NV:*<br>• MolDX: MGMT Promoter Methylation Analysis (L36188). *Companion article A57432 can be accessed directly from the LCD.* |
| ***miR-31now™*** *(0069U)* GoPath Laboratories, IL | National Government Services Inc. (NGS) LCD for Molecular Pathology Procedures (L35000) *(Applies to the indicated laboratory)*. |

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| ***MI TumorSeek*** *(81479)* Caris Life Science (AZ) | MolDX: Next-Generation Sequencing for Solid Tumors (L38121)<br>*This full assay is known as the MI Profile and it includes a large gene sequencing panel by NGS, RNA for fusion detection, microsatellite instability-high (MSI),* ***and*** *tumor mutation burden (TMB). The entire profile assay in its entirety has been approved for potential coverage by MolDX when medical necessity criteria for the MI TumorSeek component are met. If the MI TumorSeek is deemed medically necessary, the MI Profile may be approved. Separate review of additional components is not required.* |
| ***Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Testing*** *(81301, 81479, 88341, 88342)*<br>*Testing may be performed for various solid tumors, including but not limited to melanoma, non-small cell lung cancer, and colorectal cancer.* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• MolDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker Billing and Coding Guidelines for Patients with Unresectable or Metastatic Solid Tumors (A56104). *Companion LCD L36256 can be accessed directly from the article.*<br>*Laboratories in CA and NV:*<br>• MolDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker Billing and Coding Guidelines for Patients with Unresectable or Metastatic Solid Tumors (A56103). *Companion LCD L35160 can be accessed directly from the article.*<br>**Note:** This testing is sometimes performed via multi-gene NGS panels which also include MSI or dMMR testing using immunohistochemistry (IHC). |
| ***Minimal Residual Disease (MRD) Testing*** | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, UT, WY:*<br>• MolDX: Minimal Residual Disease Testing for Cancer (L38816). *This guideline states "For patients with or without cancer (as defined above), established standard-of-care MRD tests using single-gene PCR (i.e., BCR-ABL1) are covered under this policy according to testing schedules outlined in national (i.e., NCCN) or society guidelines." Companion articles A58456 and A58997 can be accessed directly from the LCD.* |
| ***Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer*** | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39007). *Companion article A58724 can be accessed directly from the LCD.* |

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| **Myelodysplastic Syndrome (MDS) FISH Testing** | MolDX: MDS FISH (L37602) *Companion article A56913 can be accessed directly from the LCD.* |
| ***myPath Melanoma Assay*** *(81479, 0090U)* Myriad Genetics (UT) | MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma (L39375). *Companion article A59181 can be accessed directly from the LCD.*<br><br>*This test has completed a TA and is listed in the DEX™ Change Healthcare Registry as "covered".* |
| ***NGS Panel Tests for Cancer: FDA-Approved/Cleared***<br><br>• ***Agilent Resolution ctDx FIRST*** *(0397U) Agilent*<br>• ***BRACAnalysis CDx*** *(81162) Myriad Genetics*<br>• ***CRCdx® RAS Mutation Detection Kit*** *(0471U) EntroGen*<br>• ***FoundationOne CDx™*** *(F1CDx) (0037U) Foundation Medicine*<br>• ***FoundationOne® Liquid CDx*** *(0239U) Foundation Medicine*<br>• ***Guardant360® CDx*** *(0242U) Guardant Health*<br>• ***MI Cancer Seek™*** *(0211U) Caris Life Sciences*<br>• ***MSK-IMPACT™*** *(0048U) Memorial Sloan Kettering Cancer Center*<br>• ***MyChoice® CDx*** *(0172U) Myriad Genetics*<br>• ***Oncomine™ Dx Target Test*** *(0022U) Thermo Fisher Scientific*<br>• ***OncoReveal™ Lung and Colon Cancer*** *and* ***OncoReveal™ CDx*** *(0523U) Pillar Biosciences*<br>• ***Praxis™ Extended RAS Panel*** *(0111U) Illumina, Inc.* | For next generation sequencing (NGS) tests **with** FDA-approval or clearance as an approved companion diagnostic or in vitro test:<br><br>• Next Generation Sequencing (NGS) (90.2)<br><br>*If the test is an FDA-designated companion diagnostic being used for* ***a different indication*** *that it was approved for (i.e., a different cancer type), then the testing* ***does not meet the NCD coverage criteria,*** *and local guidance for tumor testing should be applied (see NGS Panel Tests for Solid Tumors or Plasma-Based Panel Tests for Solid Tumors below).*<br><br>**Additional Information:**<br><br>➢ The NCD requires that the patient meets certain criteria for coverage, and that testing is "non-covered if the cancer patient does not meet the criteria."<br><br>➢ All of the tests listed to the left are found on the FDA website as an approved companion diagnostic or in vitro test. The "Indication" column in this website can be used to determine if the NCD is applicable.<br><br>➢ Testing for germline (inherited) cancer testing may be subject to this NCD, but only if the test is FDA-approved or cleared. Please note that the "Germline (Inherited) Cancer" testing section in this NCD refers only to **germline testing for inherited cancer risk**. It does **not** refer to somatic testing for targeted treatments in patients who are known to have an inherited cancer risk variant. Requests for somatic (e.g., tumor tissue) testing should only be reviewed under the "Somatic (Acquired) Cancer" section. |

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| • ***TruSight™ Oncology Comprehensive*** *(0543U) Illumina, Inc.*<br>• ***xT CDx*** *(0473U) Tempus* | |
| ***NGS Panel Tests for Myeloid Malignancies*** *(not FDA-approved or cleared as companion diagnostic tests for the cancer indication)* | *For laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38125) *Companion article A57892 can be accessed directly from the LCD.*<br>*For laboratories in CA, NV:*<br>• MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38123). *Companion article A57891 can be accessed directly from the LCD.*<br>*For laboratories in NC, SC, AL, GA, VA, WV:*<br>• MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38047). *Companion article A57837 can be accessed directly from the LCD.* |
| ***NGS Panel Tests for Solid Tumors*** *(not FDA-approved or cleared as companion diagnostic tests for the cancer indication)*<br><br>***Note****: This is for tumor tissue testing. For plasma-based [liquid biopsy] genomic profiling panel tests, see applicable row below)* | *For laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• MolDX: Next-Generation Sequencing for Solid Tumors (L38121). *Companion article A56518 can be accessed directly from the LCD.*<br>*For laboratories in CA, NV:*<br>• MolDX: Next-Generation Sequencing for Solid Tumors (L38119). *Companion article A57901 can be accessed directly from the LCD.*<br>*For laboratories in NC, SC, AL, GA, VA, WV:*<br>• MolDX: Next-Generation Sequencing for Solid Tumors (L38045). *Companion article A57831 can be accessed directly from the LCD.*<br>According to the DEX™ Change Healthcare Registry website, the following tests are noted as **potentially covered** tests by MolDX when above LCD medical necessity criteria are met:<br>✓ Guardant360 TissueNext (0334U), Guardant Health (CA)<br>✓ Solid Tumor Expanded Panel (0379U), Quest Diagnostics |

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| | ✓ Strata Select (0391U) and StrataNGS, Strata Oncology, Inc.<br><br>*Laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA:*<br><br>• Biomarkers for Oncology (L35396). *Companion article A52986 can be accessed directly from the LCD.* |
| ***Nodify CDT** (0360U)* Biodesix (CO and KS) | *Laboratory in KS:*<br><br>• MolDX: Molecular Biomarkers for Risk Stratification of Indeterminate Pulmonary Nodules Following Bronchoscopy (L39711) *Companion article A58511 can be accessed directly from the LCD. According to the DEX™ Change Healthcare Registry website, this test has completed a TA and is "**covered**".*<br><br>*Laboratory in CO:*<br><br>• LCD Biomarkers for Oncology (L35396) and companion article A52986 do not specifically address this test or CPT code. In the absence of specific local guidance for Colorado, the guidance above for Kansas should be used. |
| ***NRAS Gene Tests** (81311, 81479)* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br><br>• MolDX: NRAS Genetic Testing (L36339). *Companion article A57487 can be accessed directly from the LCD.*<br><br>*Laboratories in CA and NV:*<br><br>• MolDX: NRAS Genetic Testing (L36335). *Companion article A57486 can be accessed directly from the LCD.* |
| ***NTRK Gene Fusion Tests (NTRK1, NTRK2, and NTRK3)** (81191, 81192, 81193, 81194)* | *For laboratories in all states:*<br><br>According to the MolDX LCD L38043*, "Larotrectinib, a TRK inhibitor, has received FDA approval for *NTRK* positive (without a known resistance mutation) tumors in patients with metastatic disease or where surgical resection is likely to result in severe morbidity, and who have no satisfactory alternative treatments or that have progressed following treatment."<br><br>While this LCD is specific to the Guardant360® test and liquid biopsies, targeted *NTRK* gene fusion testing to be medically reasonable and necessary for individuals with a solid tumor for which VITRAKVI® (larotrectinib) and/or Roslytrek® (entrectinib) is being considered and the indications on the FDA label for larotrectinib or entrectinib are met. |

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| ***Omnipathology Oropharyngeal HPV PCR Test*** *(0429U)* Omnipathology (CA) | According to the Medicare National Coverage Determinations Manual, unless specifically covered by NCD, statute, or regulation, preventive services are non-covered by Medicare.<br><br>NCD 210.2.1 Screening for Cervical Cancer with Human Papillomavirus (HPV) allows coverage for HPV testing only for cervical cancer, in conjunction with a Pap smear test. Oral screening for HPV is therefore considered **not medically reasonable and necessary** under Social Security Act §1862(a)(1)(A). |
| ***OncoTarget™/OncoTreat™*** *(0019U)* Columbia University Department of Pathology & Cell Biology / Darwin Health | Molecular Pathology Procedures (L35000) *(According to this LCD, "Any genetic test reported with a CPT code, not listed above or below, is subject to individual review." Therefore, individual review would need to be performed and until specific guidance is given for this test, clinical documentation must detail how the test results will directly impact treatment, outcome and/or clinical management in the care of the beneficiary.)* |
| ***Oncotype DX® AR-V7 Nuclear Detect*** *(81479)* Epic Sciences/Genomic Health (CA) | MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells (L38643) *Companion article A58183 can be accessed directly from the LCD.*<br><br>Note: This LCD/article also addresses Biocept Target Selector HER2 Assay |
| ***Oncotype DX® Breast Recurrence Score*** *(aka Oncotype DX® Breast Cancer Assay) (81519)* Exact Sciences (CA and WI) | *Laboratory in CA:*<br>• MolDX: Oncotype DX® Breast Cancer Assay Billing and Coding Guidelines (A54480). *Companion LCD L35160 can be accessed directly from the article.*<br><br>*Laboratory in WI:*<br>• Molecular Pathology Procedures (L35000). *Companion article A56199 can be accessed directly from the LCD. See LCD entry for "**Oncology (breast), mRNA**, gene expression profiling by real-time RT-PCR of 21 genes."* |
| ***Oncotype DX® Breast DCIS*** *(0045U)* Exact Sciences (CA) | MolDX: Oncotype DX® Breast Cancer for DCIS (Genomic Health™) (L36941). *Companion article A57619 can be accessed directly from the LCD.* |
| ***Oncotype DX® Colon Cancer Recurrence Score*** *(aka, Oncotype DX® Colon Cancer Assay) (81525)* Exact Sciences (CA and WI) | *Laboratory in CA:*<br>• MolDX: Oncotype DX® Colon Cancer Coding and Billing Guidelines (A54484). *Companion LCD L35160 can be accessed directly from the article.*<br><br>*Laboratory in WI:* |

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| | • Billing and Coding: Molecular Pathology Procedures (A56199). *Companion LCD L35000 can be accessed directly from the article,* |
| ***Genomic Prostate Score® (GPS) Test*** *(aka, Oncotype DX® Genomic Prostate Score) (0047U)* MDxHealth (CA) | MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease (L38339). *Companion article A57372 can be accessed directly from the LCD.* |
| ***PanGIA Prostate*** *(0228U)* Genetics Institute of America by Entopsis *(FL)* | Molecular Pathology Procedures (L34519). |
| ***PathFinderTG® Tests,*** *Interpace Diagnostics (81479):*<br>• ***BarreGEN®***<br>• ***PancraGEN®***<br>• ***PanDNA®*** | *For PancraGen®:*<br>• Genetic Testing in Oncology: Specific Tests (L39365)<br>*For others:*<br>• Loss-of-Heterozygosity Based Topographic Genotyping with PathfinderTG® (L34864) *(applies to the indicated laboratory). Companion article* A56897 *provides procedural and diagnosis coding guidance and can be accessed directly from the LCD.* |
| ***Percepta© Bronchial Genomic Classifier*** *(81479)* Veracyte, Inc. (CA) | MolDX: Molecular Biomarkers for Risk Stratification of Indeterminate Pulmonary Nodules Following Bronchoscopy (L39678) *(Applies to the indicated performing laboratory). Companion article A59505 can be accessed directly from the LCD.* |
| ***Pervenio™ Lung NGS*** *(25 genes) (81479)* Life Technologies™ (CA) | MolDX: Next-Generation Sequencing for Solid Tumors (L38119)<br>According to the DEX™ Change Healthcare Registry website, this test is listed as "**not covered**." |
| ***Dermtech™ Melanoma Test*** *(previously called the Pigmented Lesion Assay) (0089U)* DermTech (CA) | MolDX: Pigmented Lesion Assay (L38151). *Companion article A58042 can be accessed directly from the LCD.* |
| ***PIK3CA Gene Tests*** *(81309, 81404, 0155U, 0177U)* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• Billing and Coding: MolDX: PIK3CA Gene Tests (A55602)<br>*Laboratories in CA and NV:*<br>• Billing and Coding: MolDX: PIK3CA Gene Tests (A55597) |

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| | *NOTE: Certain tests, such as the therascreen® PIK3CA RGQ PCR Kit, are FDA-approved companion diagnostic tests and may be allowed for indication(s) noted on the FDA approval list. To view FDA-approved PIK3CA tests and their corresponding medications and indications, see the FDA* List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools.) |
| ***Plasma-Based Panel Tests for Solid Tumors*** *(not otherwise specified in the policy)*<br><br>Applies to tests that are **not** FDA-designated companion diagnostic tests, or for companion diagnostic tests used for other (not FDA-designated) indications. | *Laboratories in CA and NV:*<br>• MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L39230). *Companion article A58973 can be accessed directly from the LCD.*<br><br>*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, and WY:*<br>• MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L39232). *Companion article A58975 can be accessed directly from the LCD.*<br><br>*Laboratories in IA, KS, MO, NE, IN, and MI:*<br>• MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L38168). *Companion article A57936 can be accessed directly from the LCD.*<br><br>*Laboratories in NC, SC, AL, GA, VA, TN, and WV:*<br>• MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L38043). *Companion article A57867 can be accessed directly from the LCD.*<br><br>*Laboratories in OH and KY:*<br>• MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L38065). *Companion article A57917 can be accessed directly from the LCD.*<br><br>*According to these LCDs, "Other liquid biopsies will be covered for the same indications if they display similar performance in their intended used applications to Guardant360®." Tests that do not have FDA-approval or clearance must be listed on the DEX™ Change Healthcare Registry website as a potentially covered test by MolDX for Medicare.* |
| ***Prolaris™ Prostate Cancer Prognostic Test or Genomic Assay*** *(81541)* Myriad Genetics (UT) | MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease (L38341). *Companion article A57236 can be accessed directly from LCD.*<br><br>This is a limited coverage policy for genomic tests that assess risk in localized (non-metastatic) prostate cancer. The review is focused on the Decipher® Prostate Cancer Classifier Assay. The LCD states, "Other genomic tests […] will be considered reasonable and necessary for the same indications. Analytical and clinical validity will be assessed as |

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| | part of a thorough and comprehensive technical assessment (TA) by the MolDX program and will similarly attain coverage for indications that are supported by the evidence and intended use within the scope of this policy." This test is listed on the DEX™ Change Healthcare Registry website as **covered**. |
| ***ProMark Risk Score*** *(81479)* Metamark Genetics | MolDX: ProMark Risk Score (L36706). *Companion article A57609 can be accessed directly from the LCD.* |
| ***Prosigna Breast Cancer Assay*** *(81520)* LabCorp (any state) or NanoString Technologies (WA) | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• MolDX: Breast Cancer Assay: Prosigna (L36386). *Companion article A57364 can be accessed directly from the LCD.*<br>*Laboratories in NC, SC, VA, WV, AL, TN, or GA, and LabCorp, regardless of state rendered:*<br>• MolDX: Breast Cancer Assay: Prosigna (L36125). *Companion article A56949 can be accessed directly from the LCD.*<br>*Laboratories in CA and NV:*<br>• MolDX: Breast Cancer Assay: Prosigna (L36380). *Companion article A57363 can be accessed directly from the LCD.* |
| ***RightMed® Panels*** OneOme® LLC (MN)**:**<br>• *Oncology Gene Report (0460U) and Medication Report (0461U)*<br>• *Mental Health Gene Report (0476U) and Mental Health Medication (0477U)* | Molecular Pathology Procedures (L35000). *These panels contain genes that are only covered for particular conditions, which do not include cancer (e.g., CYP2C9 only covered for multiple sclerosis). Additionally, these tests do not have demonstrated clinical validity or utility, based on peer reviewed publications or FDA approval. Therefore, they are considered* ***not medically necessary****.* |
| ***SelectMDx*** *(0339U)* MDxHealth (CA, TX) | For *laboratory in CA:*<br>• MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39005). *Companion article A58718 can be accessed directly from the LCD. This test has completed a TA from the MolDX Program and is listed in the DEX™ Change Healthcare Registry website as "covered".*<br>For *laboratory in TX:* |

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| | • Biomarkers for Oncology (L35396) and companion article A52986. *This test has completed a TA from the MolDX Program and is listed in the DEX™ Change Healthcare Registry website as "covered," therefore, there is evidence that the test has proven clinical validity/utility as listed in the LCD.* |
| ***SEPT9 Gene Tests*** *(81327)* | *Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*<br>• Billing and Coding: MolDX: SEPT9 Gene Test (A55628)<br>*Laboratories in CA and NV:*<br>• Billing and Coding: MolDX: SEPT9 Gene Test (A55623) |
| ***Signatera™*** *(0340U)* Natera (CA, TX) | For *laboratory in CA:*<br>• MolDX: Minimal Residual Disease Testing for Solid Tumor Cancers (L38814) and companion article A58454. *This test is listed in the DEX™ Change Healthcare Registry as "covered".*<br>For *laboratory in TX:*<br>• LCD Biomarkers for Oncology (L35396) and companion article A52986. According to the DEX™ Change Healthcare Registry website, this test is listed as a covered test by MolDX for Medicare, indicating that it has demonstrated clinical validity/utility, as listed in the LCD. |
| **ThyGenX** (81445), **ThyGeNEXT** (0245U), and **ThyraMIR** (0018U, 81479) Interpace Diagnostics (NJ) | Biomarkers for Oncology (L35396). *Companion article A52986 can be accessed directly from the LCD. (See the guideline specific to each test found within the LCD.)* |
| **Thyroseq Genomic Classifier** (0026U) Sonic Healthcare (NY) | Thyroid Nodule Molecular Testing (L38968). *Companion article A58656 can be accessed directly from the LCD* |
| ***TissueCypher® Barrett's Esophagus Assay*** *(0108U)* Cernostics/Castle Biosciences (PA) | Biomarkers for Oncology (L35396). *(Applies to the indicated performing laboratory)* |
| **Additional Tests That Are Not Covered** | |

***ColonAiQ*** *(0453U)* Breakthrough Genomics (CA)

***ColoScape™*** *(0368U)* DiaCarta Clinical Lab (CA)

***Dawn IO Melanoma*** *(0357U)* Intervenn (CA)

***DCISionRT®*** *(0295U)* PreludeDx™ (CA)

***EarlyTect® Bladder Cancer Detection*** *(EarlyTect® BCD) (0452U)* Promis Diagnostics (CA)

***EpiSwitch® Checkpoint-inhibitor Response Test (CiRT)*** *(0332U)* Next Bio Research Services (VA)

***Insight TNBCtype™*** *(0153U)* Insight Molecular Labs/Oncocyte Corporation (TN, CA)

***MPS*** *(Mi-Prostate Score, previously MiPS) (0113U)* MLabs (MI)

**mRNA CancerDetect™** (0296U) Viome Life Sciences (WA)

***MyAML*** *(0050U*) Laboratory for Personalized Molecular Medicine (CA)

***myChoice® HRD*** Myriad Genetics (UT)

***Northstar Response™*** *(0486U)*

***Oncuria® Detect*** *(0365U),* ***Oncuria® Monitor*** *(0366U),* ***Oncuria® Predict*** *(0367U*) DiaCarta Clinical Lab (CA)

***PGDx elio Plasma Focus*** *(0562U)* Labcorp

The MolDX Program requires tests to complete a TA to provide evidence of analytical and clinical validity, and clinical utility. Reimbursement is only allowed for “approved tests… for dates of service consistent with the effective date of the coverage determination” after MolDX review. The results of these TAs are published on the DEX™ Change Healthcare Registry website, with a “covered” or “not covered” determination.

According to the DEX™ Registry, these tests are listed as “not covered” or they do not have a coverage determination and are therefore considered **not medically necessary**.

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| ***PROSTOX™-Ultra*** *(0534U)* MiraDX (CA)<br><br>***Resolution ctDx Lung*** *(0179U)* Agilent/Resolution Biosciences (WA)<br><br>***Reveal Lung Nodule Characterization*** *(0092U)* MagArray, Inc. (CA) | |
| ***HelioLiver*** *(0333U)* Fulgent Therapeutics (CA and TX) | ***California*****:** LCD L35160 states that reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review. According to the DEX™ Change Healthcare Registry website, this test is "not covered".<br><br>***Texas*****:** This test is not listed in the LCD for *Biomarkers for Oncology* (L35396) or companion article (A52986) as a covered test. Under this LCD, additional considerations also include FDA labeling and NCCN recommendations. This test does not have FDA approval or clearance, and NCCN guidelines for Hepatocellular Carcinoma (v.2.2023) do not recommend it. Therefore, this test is considered **not medically necessary.** |
| ***Auria®*** *(0458U)* Namida Lab (AR)<br><br>***Galleri®*** *(81479)* Grail, Inc. (CA) | According to *Title XVIII of the Social Security Act, Section 1862(a)(1)(A)*: " ...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..." Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded from Medicare coverage and are therefore considered **not medically necessary**. |
| ***CxBladder Triage, Triage Plus*** *(previously Detect+),* ***Detect,*** *and* ***Monitor*** *(0363U, 0420U, 0012M, 0013M)* Pacific Edge Diagnostics (PA) | • Genetic Testing in Oncology: Specific Tests (L39365) |
| ***BBDRisk Dx™*** *(0067U)* Silbiotech (MD)<br><br>***LC-MS/MS Targeted Proteomic Assay****, (0174U)* OncoOmicDx/mProbe | • Biomarkers for Oncology (L35396)<br><br>Regarding the BBDRisk DX™ and LC-MS/MS Targeted Proteomic Assay tests, this LCD states, "…biomarkers must have proven clinical validity/utility (CVU)." The biomarkers included in these tests do not have proven clinical validity/utility. Therefore, they are considered **not medically necessary**. |

## POLICY GUIDELINES

### Important Notes Regarding Diagnostic Laboratory and Genetic Testing Services

**Medicare and Medical Necessity**

According to Medicare guidelines, Medicare coverage is contingent upon the services meeting certain requirements to determine medical necessity. In order to be considered a covered service, Medicare requires that the service in question:

- Fall within a defined Medicare benefit category[1,2]
- Not be excluded from coverage by statute, regulation, National Coverage Determination, (NCD), or Local Coverage Determination (LCD)[2]
- Be considered medically necessary, as required per the Social Security Act, §1862(a)(1)(A). This means the service must be considered reasonable and necessary in the diagnosis or treatment of an illness or injury, or to rule out or confirm a suspected diagnosis because the patient has signs and/or symptoms;[3,4] This also means services determined to be not medically necessary for any reason (including lack of safety and efficacy because it is an investigational service) are non-covered.[5]
- Be ordered by a physician who is treating the beneficiary[6,7]
- Provide data that would be directly used in the management of a beneficiary's specific medical problem[6,7]

In order for the referring physician to effectively manage their patient's specific medical problem using genetic or molecular diagnostic testing, the genetic tests performed must be used to assist in the management/treatment of the beneficiary. Therefore, it is important for referring physicians to be familiar with all specific genetic tests they order to ensure all test result components are clinically actionable.

In addition to the above Medicare requirements, when making coverage decision policies, under Chapter 13 of the Medicare Program Integrity Manual, Medicare allows contractors to consider a service "reasonable and necessary" when the service is appropriate for the member's condition. This includes appropriateness in duration, frequency, and that the service is furnished in accordance with accepted standards of medical practice for the condition, furnished in a setting appropriate to the medical needs and condition, ordered and furnished by qualified personnel, that the service meets, but does not exceed, the medical need; and is at least as beneficial as an existing and available medically appropriate alternative.[21]

**Services Excluded from Coverage**

Tests performed in the absence of signs, symptoms, complaints, personal history of disease, or injury are not covered, except when there is a statutory provision that explicitly covers a specific screening test. Tests that confirm a diagnosis or known information, and tests to determine risk for developing a disease or condition are also excluded test services.(8-11)

**Molecular Diagnostic Services Program (MolDX)**

The Medicare Molecular Diagnostic Services Program (MolDX) was developed in 2011 to identify and establish coverage and reimbursement for molecular diagnostic tests and is maintained by Palmetto GBA. Palmetto evaluates genetic tests to determine analytical and clinical validity and clinical utility, as well as confirming that each test meets Medicare criteria

(described below). Palmetto MolDX guidelines provide assessments and indicate coverage or non-coverage of the test.[12-15]**For Testing Performed Outside of the Medicare Advantage Organization's Service Area**

"A MAC outside of the plan's service area sometimes has exclusive jurisdiction over a Medicare covered item or service. In some instances, one Medicare A/B MAC processes all of the claims for a particular Medicare-covered item or service for all Medicare beneficiaries around the country. This generally occurs when there is only one supplier of a particular item, medical device or diagnostic test (for example; certain pathology and lab tests furnished by independent laboratories). In this situation, MA plans must follow the coverage requirements or LCD of the MAC that enrolled the supplier and processes all of the Medicare claims for that item, test or service."[15]

In addition, "Jurisdiction of claims for laboratory services furnished by an independent laboratory normally lies with the carrier serving the area in which the laboratory test is performed. However, there are some situations where a regional or national lab chain jurisdiction is with a single carrier."[16]

**REQUIRED DOCUMENTATION**

The following information is required in order to determine medical necessity and potential Medicare coverage for a genetic or molecular diagnostic test. *[See Title XVIII of the Social Security Act, §1833(e), which states no payment may be made unless information necessary to determine payment has been submitted)]*

1. The specific name of the genetic or molecular diagnostic test or panel;
    a. The DEX Z-code as assigned by DEX™ Diagnostics Exchange and/or a copy of the decision letter by the MolDX Program would also be beneficial in making timely and efficient coverage determinations;
2. Name of the performing laboratory;
3. The exact gene(s) and/or variants being tested (if applicable);
4. Applicable CPT and/or HCPCS code(s);
5. Brief explanation of how the results of genetic testing are necessary to guide treatment decisions relevant to the member's personal medical history. Tests performed for the following purposes are a few examples:
    - Diagnose an illness when signs/symptoms are displayed; or
    - Rule out a diagnosis when signs/symptoms are displayed; or
    - Guide treatment planning for a previously diagnosed illness (i.e., whether to perform surgery, determine chemotherapy treatment, choose between medication options, etc.); and,
6. Medical records relevant to the testing being performed. This includes:
    - History and physical examinations by the referring physician;
    - Conventional testing and outcomes; and
    - Conservative treatment provided, if applicable.

## CROSS REFERENCES

1. Genetic and Molecular Diagnostics – Testing for Inherited Cancer Risk, Genetic Testing, Policy No. M-GT02

2. Genetic and Molecular Diagnostics – Next Generation Sequencing, Genetic Panels, and Biomarker Testing, Genetic Testing, Policy No. M-GT64
3. Chemoresistance and Chemosensitivity Assays (CSRAs), Laboratory, Policy No. M-LAB06
4. Multimarker and Proteomics-based Serum Testing Related to Ovarian Cancer, Laboratory, Policy No. M-LAB60
5. Laboratory and Genetic Testing for Use of Fluoropyrimidine Chemotherapy (5-FU and Capecitabine) in Patients with Cancer, Laboratory, Policy No. M-LAB64

## REFERENCES


1. Medicare Coverage Determination Process
2. Medicare Managed Care Manual, Ch. 4 - Benefits and Beneficiary Protections, §10.2 - Basic Rule
3. Title XVIII of the Social Security Act, §1862(a)(1)(A)
4. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §20 - Services Not Reasonable and Necessary
5. Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, Subsection A
6. 42 CFR §410.32(a)
7. Medicare Benefit Policy Manual, Ch. 15 – Covered Medical and Other Health Services, §80.1 - Clinical Laboratory Services
8. Federal Register / Vol. 66, No. 226 / Friday, November 23, 2001
9. Medicare Claims Processing Manual, Chapter 16 – Laboratory Services, §120.1, Negotiated Rulemaking Implementation, see section regarding "Clarification of the Use of the Term 'Screening' or 'Screen'"
10. Medicare National Coverage Determinations (NCD) Coding Policy Manual and Change Report January 2013
11. Palmetto GBA MolDX Program
12. Noridian Healthcare Solutions - Palmetto GBA MolDX Program for Jurisdiction F
13. Molecular Diagnostics Program (MolDX®) Manual
14. Palmetto GBA Molecular Diagnostic Tests and Medicare web page
15. Medicare Managed Care Manual, Ch. 4 - Benefits and Beneficiary Protections, §90.4.1 - MACS with Exclusive Jurisdiction over a Medicare Item or Service
16. Medicare Claims Processing Manual, Chapter 1 - General Billing Requirements, §10.1.5.4 - Independent Laboratories
17. Novitas, Biomarkers for Oncology (A52986) *(This reference can be found on the Medicare Coverage Database website)*
18. Retired Noridian: Molecular Genetic Testing (A52932)
19. Palmetto GBA MolDX: Molecular Test Panel Edit Alert
20. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, §50.5 - Jurisdiction of Laboratory Claims
21. Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, §13.5.4 - Reasonable and Necessary Provision in an LCD

## CODING

**NOTE:** CPT® codes for molecular genetic testing may be non-specific, including the CPT range 81400-81408. Many of the tests listed represented by these codes are not covered by Medicare.[18] In order to properly adjudicate claims for molecular genetic testing, the actual test name being performed must be included in the narrative section of the claim.

For laboratories in the health plan's service area, instructions regarding the reporting of next generation sequencing (NGS), targeted tumor panels, or other panel testing, see the Noridian article, *MolDX: Defining panel services in MolDX* (A59678) for definitions and coding expectations.

In addition, HCPCS S-codes are not payable by Medicare, and therefore, are not payable for the health plan's Medicare Advantage members.

| Codes | Number | Description |
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| **CPT** | 0006M | Oncology (hepatic), mRNA expression levels of 161 genes, utilizing fresh hepatocellular carcinoma tumor tissue, with alpha-fetoprotein level, algorithm reported as a risk classifier (HeproDX™) |
| | 0007M | Oncology (gastrointestinal neuroendocrine tumors), real-time PCR expression analysis of 51 genes, utilizing whole peripheral blood, algorithm reported as a nomogram of tumor disease index (NETest) |
| | 0011M | Oncology, prostate cancer, mRNA expression assay of 12 genes (10 content and 2 housekeeping), RT-PCR test utilizing blood, plasma, and urine, algorithms to predict high-grade prostate cancer risk |
| | 0012M | Oncology (urothelial), mRNA, expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and XCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma |
| | 0013M | Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma |
| | 0016M | Oncology (bladder), mRNA, microarray gene expression profiling of 219 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as molecular subtype (luminal, luminal infiltrated, basal, basal claudin-low, neuroendocrine like) |
| | 0017M | Oncology (diffuse large B-cell lymphoma [DLBCL]), mRNA, gene expression profiling by fluorescent probe hybridization of 20 genes, formalin-fixed paraffin-embedded tissue, algorithm reported as cell of origin |
| | 0020M | Oncology (central nervous system), analysis of 30000 DNA methylation loci by methylation array, utilizing DNA extracted from tumor tissue, diagnostic algorithm reported as probability of matching a reference tumor subclass |
| | 0002U | Oncology (colorectal), quantitative assessment of three urine metabolites (ascorbic acid, succinic acid and carnitine) by liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring acquisition, algorithm reported as likelihood of adenomatous polyps |
| | 0005U | Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score |

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| | 0009U | Oncology (breast cancer), ERBB2 (HER2) copy number by FISH, tumor cells from formalin fixed paraffin embedded tissue isolated using image-based dielectrophoresis (DEP) sorting, reported as ERBB2 gene amplified or non-amplified |
| | 0016U | Oncology (hematolymphoid neoplasia), RNA, BCR/ABL1 major and minor breakpoint fusion transcripts, quantitative PCR amplification, blood or bone marrow, report of fusion not detected or detected with quantitation |
| | 0017U | Oncology (hematolymphoid neoplasia), JAK2 mutation, DNA, PCR amplification of exons 12-14 and sequence analysis, blood or bone marrow, report of JAK2 mutation not detected or detected |
| | 0018U | Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of malignancy |
| | 0019U | Oncology, RNA, gene expression by whole transcriptome sequencing, formalin-fixed paraffin embedded tissue or fresh frozen tissue, predictive algorithm reported as potential targets for therapeutic agents |
| | 0021U | Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'-UTR-BMI1, CEP 164, 3'-UTR-Ropporin, Desmocollin, AURKAIP-1, CSNK2A2), multiplexed immunoassay and flow cytometry serum, algorithm reported as risk score |
| | 0022U | Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/or absence of variants and associated therapy(ies) to consider |
| | 0023U | Oncology (acute myelogenous leukemia), DNA, genotyping of internal tandem duplication, p.D835, p.I836, using mononuclear cells, reported as detection or non-detection of FLT3 mutation and indication for or against the use of midostaurin |
| | 0026U | Oncology (thyroid), DNA and mRNA of 112 genes, next-generation sequencing, fine needle aspirate of thyroid nodule, algorithmic analysis reported as a categorical result ("Positive, high probability of malignancy" or "Negative, low probability of malignancy") |
| | 0027U | JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, targeted sequence analysis exons 12-15 |
| | 0036U | Oncology (somatic mutations). Whole Exome 22,000 genes by Next Generation Sequencing. DNA extracted and analyzed from formalin fixed paraffin embedded tissue and Whole Blood. Algorithm result type is predictive and prognostic. Report of specific gene mutations, alterations as targets for therapeutic agents. |
| | 0037U | Broad next generation sequencing in vitro diagnostic device, solid malignant neoplasms, DNA analysis, 324 genes, detection of substitutions, insertion and deletion alterations (indels), copy number alterations (CNAs), and select gene rearrangements as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB), reported as presence/absence of variants and discrete levels of MSI and TMB, and associated therapy(ies) including multiple FDA-approved companion |

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| | diagnostics, using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens. |
| 0040U | BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative |
| 0045U | Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score |
| 0046U | FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative |
| 0047U | Genomic Prostate Score® (GPS) Test, MDxHealth, Inc, MDxHealth, Inc |
| 0048U | Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s) |
| 0049U | NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, quantitative |
| 0050U | Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements |
| 0067U | Oncology (breast), immunohistochemistry, protein expression profiling of 4 biomarkers (matrix metalloproteinase-1 [MMP-1], carcinoembryonic antigen-related cell adhesion molecule 6 [CEACAM6], hyaluronoglucosaminidase [HYAL1], highly expressed in cancer protein [HEC1]), formalin-fixed paraffin-embedded precancerous breast tissue, algorithm reported as carcinoma risk score |
| 0069U | Oncology (colorectal), microRNA, RT-PCR expression profiling of miR-31-3p, formalin-fixed paraffin-embedded tissue, algorithm reported as an expression score |
| 0080U | Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy |
| 0089U | Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es) |
| 0090U | Oncology (cutaneous melanoma) mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin embedded tissue, algorithm reported as a categorical result (ie, benign, indeterminate, or malignant) |
| 0091U | Oncology (colorectal) screening, cell enumeration of circulating tumor cells, utilizing whole blood, algorithm, for the presence of adenoma or cancer, reported as a positive or negative result |

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| | 0092U | Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy |
| | 0108U | Gastroenterology (Barrett's esophagus), whole slide–digital imaging, including morphometric analysis, computer-assisted quantitative immunolabeling of 9 protein biomarkers (p16, AMACR, p53, CD68, COX-2, CD45RO, HIF1a, HER-2, K20) and morphology, formalin-fixed paraffin-embedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer |
| | 0111U | Oncology (colon cancer), targeted KRAS (codons 12, 13, and 61) and NRAS (codons 12, 13, and 61) gene analysis utilizing formalin-fixed paraffin-embedded tissue |
| | 0113U | Oncology (prostate), measurement of PCA3 and TMPRSS2-ERG in urine and PSA in serum following prostatic massage, by RNA amplification and fluorescence based detection, algorithm reported as risk score |
| | 0120U | Oncology (B-cell lymphoma classification), mRNA, gene expression profiling by fluorescent probe hybridization of 58 genes (45 content and 13 housekeeping genes), formalin-fixed paraffin-embedded tissue, algorithm reported as likelihood for primary mediastinal B-cell lymphoma (PMBCL) and diffuse large B-cell lymphoma (DLBCL) with cell of origin subtyping in the latter |
| | 0138U | BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) mRNA sequence analysis (List separately in addition to code for primary procedure) (Use 0138U in conjunction with 81162) |
| | 0153U | Oncology (breast), mRNA, gene expression profiling by next-generation sequencing of 101 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a triple negative breast cancer clinical subtype(s) with information on immune cell involvement |
| | 0154U | Oncology (urothelial cancer), RNA, analysis by real-time RT-PCR of the FGFR3 (fibroblast growth factor receptor 3) gene analysis [ie, p.R248C (c.742C>T), p.S249C (c.746C>G), p.G370C (c.1108G>T), p.Y373C (c.1118A>G), FGFR3-TACC3v1, and FGFR3-TACC3v3] utilizing formalin-fixed paraffin-embedded (FFPE) urothelial cancer tumor tissue, reported as FGFR gene alteration status |
| | 0155U | Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3-kinase, catalytic subunit alpha) gene analysis (ie, p.C420R, p.E542K, p.E545A, p.E545D [g.1635G>T only], p.E545G, p.E545K, p.Q546E, p.Q546R, p.H1047L, p.H1047R, p.H1047Y), utilizing formalin-fixed paraffin-embedded (FFPE) breast tumor tissue, reported as PIK3CA gene mutation status |
| | 0163U | Oncology (colorectal) screening, biochemical enzyme-linked immunosorbent assay (ELISA) of 3 plasma or serum proteins (teratocarcinoma derived growth factor-1 [TDGF-1, Cripto-1], carcinoembryonic antigen [CEA], extracellular matrix protein [ECM]), with demographic data (age, gender, CRC-screening compliance) using a proprietary algorithm and reported as likelihood of CRC or advanced adenomas |

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| | 0171U | Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence |
| | 0172U | Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score |
| | 0174U | Oncology (solid tumor), mass spectrometric 30 protein targets, formalin-fixed paraffin-embedded tissue, prognostic and predictive algorithm reported as likely, unlikely, or uncertain benefit of 39 chemotherapy and targeted therapeutic oncology agents |
| | 0177U | Oncology (breast cancer), DNA, PIK3CA (phosphatidylinositol-4,5-bisphosphate 3kinase catalytic subunit alpha) gene analysis of 11 gene variants utilizing plasma, reported as PIK3CA gene mutation status |
| | 0179U | Oncology (solid tumor as indicated by the label), somatic mutation analysis of BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) and analysis of homologous recombination deficiency pathways, DNA, formalin-fixed paraffin-embedded tissue, algorithm quantifying tumor genomic instability score |
| | ~~0204U~~ | ~~Oncology (thyroid), mRNA, gene expression analysis of 593 genes (including BRAF, RAS, RET, PAX8, and NTRK) for sequence variants and rearrangements, utilizing fine needle aspirate, reported as detected or not detected~~ (Deleted 07/01/2024) |
| | 0211U | Oncology (pan-tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, interpretative report for single nucleotide variants, copy number alterations, tumor mutational burden, and microsatellite instability, with therapy association |
| | 0228U | Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer |
| | 0229U | BCAT1 (Branched chain amino acid transaminase 1) and IKZF1 (IKAROS family zinc finger 1) (eg, colorectal cancer) promoter methylation analysis |
| | 0239U | Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free DNA, analysis of 311 or more genes, interrogation for sequence variants, including substitutions, insertions, deletions, select rearrangements, and copy number variations |
| | 0242U | Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 55-74 genes, interrogation for sequence variants, gene copy number amplifications, and gene rearrangements |
| | 0244U | Oncology (solid organ), DNA, comprehensive genomic profiling, 257 genes, interrogation for single-nucleotide variants, insertions/deletions, copy number alterations, gene rearrangements, tumor-mutational burden and microsatellite instability, utilizing formalin-fixed paraffin-embedded tumor tissue |

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| | 0245U | Oncology (thyroid), mutation analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers using next-generation sequencing, fine needle aspirate, report includes associated risk of malignancy expressed as a percentage |
| | 0249U | Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report |
| | 0250U | Oncology (solid organ neoplasm), targeted genomic sequence DNA analysis of 505 genes, interrogation for somatic alterations (SNVs [single nucleotide variant], small insertions and deletions, one amplification, and four translocations), microsatellite instability and tumor-mutation burden |
| | 0261U | Oncology (colorectal cancer), image analysis with artificial intelligence assessment of 4 histologic and immunohistochemical features (CD3 and CD8 within tumor-stroma border and tumor core), tissue, reported as immune response and recurrence-risk score |
| | 0285U | Oncology, response to radiation, cell-free DNA, quantitative branched chain DNA amplification, plasma, reported as a radiation toxicity score |
| | 0287U | Oncology (thyroid), DNA and mRNA, next-generation sequencing analysis of 112 genes, fine needle aspirate or formalin-fixed paraffin-embedded (FFPE) tissue, algorithmic prediction of cancer recurrence, reported as a categorical risk result (low, intermediate, high) |
| | 0288U | Oncology (lung), mRNA, quantitative PCR analysis of 11 genes (BAG1, BRCA1, CDC6, CDK2AP1, ERBB3, FUT3, IL11, LCK, RND3, SH3BGR, WNT3A) and 3 reference genes (ESD, TBP, YAP1), formalin-fixed paraffin-embedded (FFPE) tumor tissue, algorithmic interpretation reported as a recurrence risk score |
| | 0295U | Oncology (breast ductal carcinoma in situ), protein expression profiling by immunohistochemistry of 7 proteins (COX2, FOXA1, HER2, Ki-67, p16, PR, SIAH2), with 4 clinicopathologic factors (size, age, margin status, palpability), utilizing formalin-fixed paraffin- embedded (FFPE) tissue, algorithm reported as a recurrence risk score |
| | 0296U | Oncology (oral and/or oropharyngeal cancer), gene expression profiling by RNA sequencing at least 20 molecular features (eg, human and/or microbial mRNA), saliva, algorithm reported as positive or negative for signature associated with malignancy |
| | 0297U | Oncology (pan tumor), whole genome sequencing of paired malignant and normal DNA specimens, fresh or formalinfixed paraffin-embedded (FFPE) tissue, blood or bone marrow, comparative sequence analyses and variant identification |
| | 0298U | Oncology (pan tumor), whole transcriptome sequencing of paired malignant and normal RNA specimens, fresh or formalin-fixed paraffin-embedded (FFPE) tissue, blood or bone marrow, comparative sequence analyses and expression level and chimeric transcript identification |
| | 0299U | Oncology (pan tumor), whole genome optical genome mapping of paired malignant and normal DNA specimens, fresh frozen tissue, blood, or bone marrow, comparative structural variant identification |

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| | 0300U | Oncology (pan tumor), whole genome sequencing and optical genome mapping of paired malignant and normal DNA specimens, fresh tissue, blood, or bone marrow, comparative sequence analyses and variant identification |
| | 0306U | Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis, cell-free DNA, initial (baseline) assessment to determine a patient specific panel for future comparisons to evaluate for MRD |
| | 0307U | Oncology (minimal residual disease [MRD]), next-generation targeted sequencing analysis of a patient-specific panel, cell-free DNA, subsequent assessment with comparison to previously analyzed patient specimens to evaluate for MRD |
| | 0314U | Oncology (cutaneous melanoma), mRNA gene expression profiling by RT-PCR of 35 genes (32 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical result (ie, benign, intermediate, malignant) |
| | 0315U | Oncology (cutaneous squamous cell carcinoma), mRNA gene expression profiling by RT-PCR of 40 genes (34 content and 6 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as a categorical risk result (ie, Class 1, Class 2A, Class 2B) |
| | 0317U | Oncology (lung cancer), four-probe FISH (3q29, 3p22.1, 10q22.3, 10cen) assay, whole blood, predictive algorithm generated evaluation reported as decreased or increased risk for lung cancer |
| | 0326U | Targeted genomic sequence analysis panel, solid organ neoplasm, cell-free circulating DNA analysis of 83 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden |
| | 0329U | Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with and DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations |
| | 0331U | Oncology (hematolymphoid neoplasia), optical for copy number alterations and gene rearrangements utilizing DNA from blood or bone marrow, report of clinically significant alternations |
| | 0332U | Oncology (pan-tumor), genetic profiling of 8 DNA-regulatory (epigenetic) markers by quantitative polymerase chain reaction (qPCR), whole blood, reported as a high or low probability of responding to immune checkpoint–inhibitor therapy |
| | 0333U | Oncology (liver), surveillance for hepatocellular carcinoma (HCC) in highrisk patients, analysis of methylation patterns on circulating cell-free DNA (cfDNA) plus measurement of serum of AFP/AFP-L3 and oncoprotein des-gammacarboxy-prothrombin (DCP), algorithm reported as normal or abnormal result |
| | 0334U | Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin embedded (FFPE) tumor tissue, DNA analysis, 84 or more genes, |

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| | interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden |
| 0338U | Oncology (solid tumor), circulating tumor cell selection, identification, morphological characterization, detection and enumeration based on differential EpCAM, cytokeratins 8, 18, and 19, and CD45 protein biomarkers, and quantification of HER2 protein biomarker–expressing cells, peripheral blood |
| 0339U | Oncology (prostate), mRNA expression profiling of HOXC6 and DLX1, reverse transcription polymerase chain reaction (RT-PCR), first-void urine following digital rectal examination, algorithm reported as probability of high-grade cancer |
| 0340U | Oncology (pan-cancer), analysis of minimal residual disease (MRD) from plasma, with assays personalized to each patient based on prior next-generation sequencing of the patient's tumor and germline DNA, reported as absence or presence of MRD, with disease-burden correlation, if appropriate |
| 0343U | Oncology (prostate), exosome-based analysis of 442 small noncoding RNAs (sncRNAs) by quantitative reverse transcription polymerase chain reaction (RT-qPCR), urine, reported as molecular evidence of no-, low-, intermediate- or high-risk of prostate cancer |
| 0356U | Oncology (oropharyngeal or anal), evaluation of 17 DNA biomarkers using droplet digital PCR (ddPCR), cell-free DNA, algorithm reported as a prognostic risk score for cancer recurrence |
| 0359U | Oncology (prostate cancer), analysis of all prostate-specific antigen (PSA) structural isoforms by phase separation and immunoassay, plasma, algorithm reports risk of cancer |
| 0360U | Oncology (lung), enzyme-linked immunosorbent assay (ELISA) of 7 autoantibodies (p53, NY-ESO-1, CAGE, GBU4-5, SOX2, MAGE A4, and HuD), plasma, algorithm reported as a categorical result for risk of malignancy |
| 0362U | Oncology (papillary thyroid cancer), gene-expression profiling via targeted hybrid capture–enrichment RNA sequencing of 82 content genes and 10 housekeeping genes, fine needle aspirate or formalin-fixed paraffin embedded (FFPE) tissue, algorithm reported as one of three molecular subtypes |
| 0363U | Oncology (urothelial), mRNA, gene-expression profiling by real-time quantitative PCR of 5 genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm incorporates age, sex, smoking history, and macrohematuria frequency, reported as a risk score for having urothelial carcinoma |
| 0364U | Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (PCR) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (MRD) with quantitation of disease burden, when appropriate |
| 0365U | Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm, including patient's age, race and gender, reported as a probability of harboring urothelial bladder cancer |

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| | 0366U | Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of recurrent bladder cancer |
| | 0367U | Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm reported as a risk score for probability of rapid recurrence of recurrent or persistent cancer following transurethral resection |
| | 0368U | Oncology (colorectal cancer), evaluation for mutations of APC, BRAF, CTNNB1, KRAS, NRAS, PIK3CA, SMAD4, and TP53, and methylation markers (MYO1G, KCNQ5, C9ORF50, FLI1, CLIP4, ZNF132 and TWIST1), multiplex quantitative polymerase chain reaction (qPCR), circulating cell-free DNA (cfDNA), plasma, report of risk score for advanced adenoma or colorectal cancer |
| | 0375U | Oncology (ovarian), biochemical assays of 7 proteins (follicle stimulating hormone, human epididymis protein 4, apolipoprotein A-1, transferrin, beta-2 macroglobulin, prealbumin [ie, transthyretin], and cancer antigen 125), algorithm reported as ovarian cancer risk score |
| | 0376U | Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancerspecific mortality, includes predictive algorithm to androgen deprivationtherapy response, if appropriate |
| | 0379U | Targeted genomic sequence analysis panel, solid organ neoplasm, DNA (523 genes) and RNA (55 genes) by nextgeneration sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden |
| | 0387U | Oncology (melanoma), autophagy and beclin 1 regulator 1 (AMBRA1) and loricrin (AMLo) by immunohistochemistry, formalinfixed paraffin-embedded (FFPE) tissue, report for risk of progression |
| | 0388U | Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection |
| | 0391U | Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splicesite variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score |
| | 0395U | Oncology (lung), multi-omics (microbial DNA by shotgun next generation sequencing and carcinoembryonic antigen and osteopontin by immunoassay), plasma, algorithm reported as malignancy risk for lung nodules in early-stage disease |
| | 0398U | Gastroenterology (Barrett esophagus), P16, RUNX3, HPP1, and FBN1 DNA methylation analysis using PCR, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score for progression to high-grade dysplasia or cancer |

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| | 0403U | Oncology (prostate), mRNA, gene expression profiling of 18 genes, first-catch urine, algorithm reported as percentage of likelihood of detecting clinically significant prostate cancer |
| | 0404U | Oncology (breast), semiquantitative measurement of thymidine kinase activity by immunoassay, serum, results reported as risk of disease progression |
| | 0405U | Oncology (pancreatic), 59 methylation haplotype block markers, next-generation sequencing, plasma, reported as cancer signal detected or not detected |
| | 0406U | Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer |
| | 0409U | Oncology (solid tumor), DNA (80 genes) and RNA (36 genes), by next-generation sequencing from plasma, including single nucleotide variants, insertions/deletions, copy number alterations, microsatellite instability, and fusions, report showing identified mutations with clinical actionability |
| | 0410U | Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine enrichment, whole blood or plasma, algorithm reported as cancer detected or not detected |
| | 0413U | Oncology (hematolymphoid neoplasm), optical genome mapping for copy number alterations, aneuploidy, and balanced/complex structural rearrangements, DNA from blood or bone marrow, report of clinically significant alterations |
| | 0414U | Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (ALK, BRAF, EGFR, ERBB2, MET, NTRK1-3, RET, ROS1), and KRAS G12C and PD-L1, if performed, formalin-fixed paraffin embedded (FFPE) tissue, reported as positive or negative for each biomarker |
| | 0418U | Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score |
| | 0420U | Oncology (urothelial), mRNA expression profiling by real-time quantitative PCR of MDK, HOXA13, CDC2, IGFBP5, and CXCR2 in combination with droplet digital PCR (ddPCR) analysis of 6 single-nucleotide polymorphisms (SNPs) genes TERT and FGFR3, urine, algorithm reported as a risk score for urothelial carcinoma |
| | 0421U | Oncology (colorectal) screening, quantitative real-time target and signal amplification of 8 RNA markers (GAPDH, SMAD4, ACY1, AREG, CDH1, KRAS, TNFRSF10B, EGLN2) and fecal hemoglobin, algorithm reported as a positive or negative for colorectal cancer risk |
| | 0422U | Oncology (pan-solid tumor), analysis of DNA biomarker response to anti-cancer therapy using cell-free circulating DNA, biomarker comparison to a previous baseline pre-treatment cell-free circulating DNA analysis using next-generation sequencing, algorithm reported as a quantitative change from baseline, including specific alterations, if appropriate |
| | 0424U | Oncology (prostate), exosomebased analysis of 53 small noncoding RNAs (sncRNAs) by quantitative reverse transcription polymerase chain reaction |

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| | (RTqPCR), urine, reported as no molecular evidence, low-, moderate- or elevated-risk of prostate cancer |
| ~~0428U~~ | ~~Oncology (breast), targeted hybrid-capture genomic sequence analysis panel, circulating tumor DNA (ctDNA) analysis of 56 or more genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutation burden~~ (Deleted 1/1/2025) |
| 0429U | Human papillomavirus (HPV), oropharyngeal swab, 14 high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) |
| 0433U | Oncology (prostate), 5 DNA regulatory markers by quantitative PCR, whole blood, algorithm, including prostate-specific antigen, reported as likelihood of cancer |
| 0436U | Oncology (lung), plasma analysis of 388 proteins, using aptamerbased proteomics technology, predictive algorithm reported as clinical benefit from immune checkpoint inhibitor therapy |
| 0444U | Oncology (solid organ neoplasia), targeted genomic sequence panel of 361 genes, interrogation for gene fusions, translocations, or other rearrangements, using DNA from formalin-fixed paraffin-embedded (DDPE) tumor tissue, report of clinically significant variant(s) |
| ~~0448U~~ | ~~Oncology (lung and colon cancer), DNA, qualitative, next generation sequencing detection of single nucleotide variants and deletions in EGFR and KRAS genes, formalin-fixed paraffin embedded (FFPE) solid tumor samples, reported as presence or absence of targeted mutation(s), with recommended therapeutic options~~ (Deleted 1/1/2025) |
| 0450U | Oncology (multiple myeloma), liquid chromatography with tandem mass spectrometry (LCMS/MS), monoclonal paraprotein sequencing analysis, serum, results reported as baseline presence or absence of detectable clonotypic peptides |
| 0451U | Oncology (multiple myeloma), LCMS/MS, peptide ion quantification, serum, results compared with baseline to determine monoclonal paraprotein abundance |
| 0452U | Oncology (bladder), methylated PENK DNA detection by linear target enrichment-quantitative methylation-specific real-time PCR (LTE-qMSP), urine, reported as likelihood of bladder cancer |
| 0453U | Oncology (colorectal cancer), cellfree DNA (cfDNA), methylation based quantitative PCR assay (SEPTIN9, IKZF1, BCAT1, Septin9-2, VAV3, BCAN), plasma, reported as presence or absence of circulating tumor DNA (ctDNA) |
| 0458U | Oncology (breast cancer), S100A8 and S100A9, by enzymelinked immunosorbent assay (ELISA), tear fluid with age, algorithm reported as a risk score |
| 0460U | Oncology, whole blood or buccal, DNA single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, with variant analysis and reported phenotypes |
| 0461U | Oncology, pharmacogenomic analysis of single-nucleotide polymorphism (SNP) genotyping by real-time PCR of 24 genes, whole blood or buccal swab, with variant analysis, including impacted gene-drug interactions and reported phenotypes |

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| | 0464U | Oncology (colorectal) screening, quantitative real-time target and signal amplification, methylated DNA markers, including LASS4, LRRC4 and PPP2R5C, a reference marker ZDHHC1, and a protein marker (fecal hemoglobin), utilizing stool, algorithm reported as a positive or negative result |
| | 0465U | Oncology (urothelial carcinoma), DNA, quantitative methylation specific PCR of 2 genes (ONECUT2, VIM), algorithmic analysis reported as positive or negative |
| | 0467U | Oncology (bladder), DNA, next generation sequencing (NGS) of 60 genes and whole genome aneuploidy, urine, algorithms reported as minimal residual disease (MRD) status positive or negative and quantitative disease burden |
| | 0470U | Oncology (oropharyngeal), detection of minimal residual disease by next-generation sequencing (NGS) based quantitative evaluation of 8 DNA targets, cell-free HPV 16 and 18 DNA from plasma |
| | 0471U | Oncology (colorectal cancer), qualitative real-time PCR of 35 variants of KRAS and NRAS genes (exons 2, 3, 4), formalin fixed paraffin-embedded (FFPE), predictive, identification of detected mutations |
| | 0473U | Oncology (solid tumor), next generation sequencing (NGS) of DNA from formalin-fixed paraffin embedded (FFPE) tissue with comparative sequence analysis from a matched normal specimen (blood or saliva), 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor-mutation burden |
| | 0478U | Oncology (non-small cell lung cancer), DNA and RNA, digital PCR analysis of 9 genes (EGFR, KRAS, BRAF, ALK, ROS1, RET, NTRK 1/2/3, ERBB2, and MET) in formalin-fixed paraffin-embedded (FFPE) tissue, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, and reported as actionable detected variants for therapy selection |
| | 0481U | IDH1 (isocitrate dehydrogenase 1 [NADP+]), IDH2 (isocitrate dehydrogenase 2 [NADP+]), and TERT (telomerase reverse transcriptase) promoter (eg, central nervous system [CNS] tumors), next-generation sequencing (single-nucleotide variants [SNV], deletions, and insertions) |
| | 0485U | Oncology (solid tumor), cell-free DNA and RNA by next-generation sequencing, interpretative report for germline mutations, clonal hematopoiesis of indeterminate potential, and tumor-derived single-nucleotide variants, small insertions/deletions, copy number alterations, fusions, microsatellite instability, and tumor mutational burden |
| | 0486U | Oncology (pan-solid tumor), nextgeneration sequencing analysis of tumor methylation markers present in cell-free circulating tumor DNA, algorithm reported as quantitative measurement of methylation as a correlate of tumor fraction |
| | 0487U | Oncology (solid tumor), cell-free circulating DNA, targeted genomic sequence analysis panel of 84 genes, interrogation for sequence variants, aneuploidycorrected gene copy number amplifications and losses, gene rearrangements, and microsatellite instability |
| | 0490U | Oncology (cutaneous or uveal melanoma), circulating tumor cell selection, morphological characterization and enumeration based on differential CD146, |

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| | high molecular–weight melanoma associated antigen, CD34 and CD45 protein biomarkers, peripheral blood |
| 0491U | Oncology (solid tumor), circulating tumor cell selection, morphological characterization and enumeration based on differential epithelial cell adhesion molecule (EpCAM), cytokeratins 8, 18, and 19, CD45 protein biomarkers, and quantification of estrogen receptor (ER) protein biomarker–expressing cells, peripheral blood |
| 0492U | Oncology (solid tumor), circulating tumor cell selection, morphological characterization and enumeration based on differential epithelial cell adhesion molecule (EpCAM), cytokeratins 8, 18, and 19, CD45 protein biomarkers, and quantification of PD-L1 protein biomarker–expressing cells, peripheral blood |
| 0495U | Oncology (prostate), analysis of circulating plasma proteins (tPSA, fPSA, KLK2, PSP94, and GDF15), germline polygenic risk score (60 variants), clinical information (age, family history of prostate cancer, prior negative prostate biopsy), algorithm reported as risk of likelihood of detecting clinically significant prostate cancer |
| 0496U | Oncology (colorectal), cell-free DNA, 8 genes for mutations, 7 genes for methylation by real-time RT-PCR, and 4 proteins by enzyme-linked immunosorbent assay, blood, reported positive or negative for colorectal cancer or advanced adenoma risk |
| 0497U | Oncology (prostate), mRNA gene expression profiling by real-time RT-PCR of 6 genes (FOXM1, MCM3, MTUS1, TTC21B, ALAS1, and PPP2CA), utilizing formalin fixed paraffin-embedded (FFPE) tissue, algorithm reported as a risk score for prostate cancer |
| 0498U | Oncology (colorectal), next generation sequencing for mutation detection in 43 genes and methylation pattern in 45 genes, blood, and formalin-fixed paraffin-embedded (FFPE) tissue, report of variants and methylation pattern with interpretation |
| 0499U | Oncology (colorectal and lung), DNA from formalin-fixed paraffin embedded (FFPE) tissue, next generation sequencing of 8 genes (NRAS, EGFR, CTNNB1, PIK3CA, APC, BRAF, KRAS, and TP53), mutation detection |
| 0501U | Oncology (colorectal), blood, quantitative measurement of cellfree DNA (cfDNA) |
| 0502U | Human papillomavirus (HPV), E6/E7 markers for high-risk types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68), cervical cells, branched-chain capture hybridization, reported as negative or positive for high risk for HPV |
| 0506U | Gastroenterology (Barrett's esophagus), esophageal cells, DNA methylation analysis by next-generation sequencing of at least 89 differentially methylated genomic regions, algorithm reported as likelihood for Barrett's esophagus |
| 0507U | Oncology (ovarian), DNA, whole genome sequencing with 5-hydroxymethylcytosine (5hmC) enrichment, using whole blood or plasma, algorithm reported as cancer detected or not detected |
| 0510U | Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced RNA whole transcriptome data, reported as probability of predicted molecular subtype |

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| | 0512U | Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) status, formalin-fixed paraffin embedded (FFPE) tissue, reported as increased or decreased probability of MSI-high (MSI-H) |
| | 0513U | Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (MSI) and homologous recombination deficiency (HRD) status, formalin fixed paraffin-embedded (FFPE) tissue, reported as increased or decreased probability of each biomarker |
| | 0523U | Oncology (solid tumor), DNA, qualitative, next-generation sequencing (NGS) of single-nucleotide variants (SNV) and insertion/deletions in 22 genes utilizing formalin-fixed paraffin-embedded tissue, reported as presence or absence of mutation(s), location of mutation(s), nucleotide change, and amino acid change |
| | 0530U | Oncology (pan-solid tumor), ctDNA, utilizing plasma, next-generation sequencing (NGS) of 77 genes, 8 fusions, microsatellite instability, and tumor mutation |
| | 0534U | Oncology (prostate), microRNA, single-nucleotide polymorphisms (SNPs) analysis by RT-PCR of 32 variants, using buccal swab, algorithm reported as a risk score |
| | 0537U | Oncology (colorectal cancer), analysis of cell-free DNA for epigenomic patterns, next-generation sequencing, >2500 differentially methylated regions (DMRs), plasma, algorithm reported as positive or negative |
| | 0538U | Oncology (solid tumor), next-generation targeted sequencing analysis, formalin-fixed paraffin embedded (FFPE) tumor tissue, DNA analysis of 600 genes, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, and copy number alterations, microsatellite instability, tumor mutation burden, reported as actionable variant |
| | 0539U | Oncology (solid tumor), cell-free circulating tumor DNA (ctDNA), 152 genes, next-generation sequencing, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, copy number alterations, and microsatellite instability, using whole-blood samples, mutations with clinical actionability reported as actionable variant |
| | 0543U | Oncology (solid tumor), next-generation sequencing of DNA from formalin-fixed paraffin-embedded (FFPE) tissue of 517 genes, interrogation for single-nucleotide variants, multi-nucleotide variants, insertions and deletions from DNA, fusions in 24 genes and splice variants in 1 gene from RNA, and tumor mutation burden |
| | 0549U | Oncology (urothelial), DNA, quantitative methylated real-time PCR of TRNA-Cys, SIM2, and NKX1-1, using urine, diagnostic algorithm reported as a probability index for bladder cancer and/or upper tract urothelial carcinoma (UTUC) |
| | 0550U | Oncology (prostate), enzyme-linked immunosorbent assays (ELISA) for total prostate-specific antigen (PSA) and free PSA, serum, combined with age, previous negative prostate biopsy status, digital rectal examination findings, |

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| | prostate volume, and image and data reporting of the prostate, algorithm reported as a risk score for the presence of high-grade prostate cancer |
| 0558U | Oncology (colorectal), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted colorectal cancer protein marker (BF7 antigen), using serum, result reported as indicative of response/no response to therapy or disease progression/regression |
| 0559U | Oncology (breast), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted breast cancer protein marker (BF9 antigen), serum, result reported as indicative of response/no response to therapy or disease progression/regression |
| 0560U | Oncology (minimal residual disease [MRD]), genomic sequence analysis, cell-free DNA, whole blood and tumor tissue, baseline assessment for design and construction of a personalized variant panel to evaluate current MRD and for comparison to subsequent MRD assessments |
| 0561U | Oncology (minimal residual disease [MRD]), genomic sequence analysis, cell-free DNA, whole blood, subsequent assessment with comparison to initial assessment to evaluate for MRD |
| 0562U | Oncology (solid tumor), targeted genomic sequence analysis, 33 genes, detection of single-nucleotide variants (SNVs), insertions and deletions, copy-number amplifications, and translocations in human genomic circulating cell-free DNA, plasma, reported as presence of actionable variants |
| 0565U | Oncology (hepatocellular carcinoma), next-generation sequencing methylation pattern assay to detect 6626 epigenetic alterations, cell-free DNA, plasma, algorithm reported as cancer signal detected or not detected |
| 0566U | Oncology (lung), qPCR-based analysis of 13 differentially methylated regions (CCDC181, HOXA7, LRRC8A, MARCHF11, MIR129-2, NCOR2, PANTR1, PRKCB, SLC9A3, TBR1_2, TRAP1, VWC2, ZNF781), pleural fluid, algorithm reported as a qualitative result |
| 0569U | Oncology (solid tumor), next-generation sequencing analysis of tumor methylation markers (>20000 differentially methylated regions) present in cell-free circulating tumor DNA (ctDNA), whole blood, algorithm reported as presence or absence of ctDNA with tumor fraction, if appropriate |
| 0571U | Oncology (solid tumor), DNA (80 genes) and RNA (10 genes), by next-generation sequencing, plasma, including single-nucleotide variants, insertions/deletions, copy-number alterations, microsatellite instability, and fusions, reported as clinically actionable variants |
| 0572U | Oncology (prostate), high-throughput telomere length quantification by FISH, whole blood, diagnostic algorithm reported as risk of prostate cancer |
| 0573U | Oncology (pancreas), 3 biomarkers (glucose, carcinoembryonic antigen, and gastricsin), pancreatic cyst lesion fluid, algorithm reported as categorical mucinous or non-mucinous |
| 81120 | IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants (eg, R132H, R132C) |
| 81121 | IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M) |

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| | 81162 | BRCA1 (BRCA1, DMA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis (ie, detection of large gene rearrangements) |
| | 81163 | BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis |
| | 81164 | BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements) |
| | 81165 | BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis |
| | 81166 | BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements) |
| | 81167 | BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements) |
| | 81168 | CCND1/IGH (t(11;14)) (eg, mantle cell lymphoma) translocation analysis, major breakpoint, qualitative and quantitative, if performed |
| | 81170 | ABL1 (ABL proto-oncogene 1, non-receptor tyrosine kinase) (eg, acquired imatinib tyrosine kinase inhibitor resistance), gene analysis, variants in the kinase domain |
| | 81175 | ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; full gene sequence |
| | 81176 | ;targeted sequence analysis (eg, exon 12) |
| | 81191 | NTRK1 (neurotrophic receptor tyrosine kinase 1) (eg, solid tumors) translocation analysis |
| | 81192 | NTRK2 (neurotrophic receptor tyrosine kinase 2) (eg, solid tumors) translocation analysis |
| | 81193 | NTRK3 (neurotrophic receptor tyrosine kinase 3) (eg, solid tumors) translocation analysis |
| | 81194 | NTRK (neurotrophic-tropomyosin receptor tyrosine kinase 1, 2, and 3) (eg, solid tumors) translocation analysis |
| | 81206 | BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative |
| | 81207 | ;minor breakpoint, qualitative or quantitative |
| | 81208 | ;other breakpoint, qualitative or quantitative |
| | 81210 | BRAF (B-Raf proto-oncogene, serine/threonine kinase) (eg, colon cancer, melanoma), gene analysis, V600E variant(s) |
| | 81212 | BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants |
| | 81216 | BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis |

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| | 81218 | CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence |
| | 81219 | CALR (calreticulin) (eg, myeloproliferative disorders), gene analysis, common variants in exon 9 |
| | 81233 | BTK (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F) |
| | 81235 | EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 LREA deletion, L858R, T790M, G719A, G719S, L861Q) |
| | 81236 | EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence |
| | 81237 | EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646) |
| | 81245 | FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; internal tandem duplication (ITD) variants (ie, exons 14, 15) |
| | 81246 | ;tyrosine kinase domain (TKD) variants (eg, D835, I836) |
| | 81261 | IGH@ (Immunoglobulin heavy chain locus) (eg, leukemias and lymphomas, B-cell), gene rearrangement analysis to detect abnormal clonal population(s); amplified methodology (eg, polymerase chain reaction) |
| | 81262 | ;direct probe methodology (eg, Southern blot) |
| | 81263 | IGH@ (Immunoglobulin heavy chain locus) (eg, leukemia and lymphoma, B-cell), variable region somatic mutation analysis |
| | 81264 | IGK@ (Immunoglobulin kappa light chain locus) (eg, leukemia and lymphoma, B-cell), gene rearrangement analysis, evaluation to detect abnormal clonal population(s) |
| | 81270 | JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant |
| | 81272 | KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, gastrointestinal stromal tumor [GIST], acute myeloid leukemia, melanoma), gene analysis, targeted sequence analysis (eg, exons 8, 11, 13, 17, 18) |
| | 81273 | KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, mastocytosis), gene analysis, D816 variant(s) |
| | 81275 | KRAS (Kirsten rat sarcoma viral oncogene homolog) (eg, carcinoma) gene analysis; variants in exon 2 (eg, codons 12 and 13) |
| | 81276 | ;additional variant(s) (eg, codon 61, codon 146) |
| | 81277 | Cytogenomic neoplasia (genome-wide) microarray analysis, interrogation of genomic regions for copy number and loss-of-heterozygosity variants for chromosomal abnormalities |
| | 81278 | IGH@/BCL2 (t(14;18)) (eg, follicular lymphoma) translocation analysis, major breakpoint region (MBR) and minor cluster region (mcr) breakpoints, qualitative or quantitative |
| | 81279 | JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13) |

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| | 81287 | MGMT (O-6-methylguanine-DNA methyltransferase) (eg, glioblastoma multiforme) promoter methylation analysis |
| | 81301 | Microsatellite instability analysis (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (eg, BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed |
| | 81305 | MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant |
| | 81309 | PIK3CA (phosphatidylinositol-4, 5-biphosphate 3-kinase, catalytic subunit alpha) (eg, colorectal and breast cancer) gene analysis, targeted sequence analysis (eg, exons 7, 9, 20) |
| | 81310 | NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, exon 12 variants |
| | 81311 | NRAS (neuroblastoma RAS viral [v-ras] oncogene homolog) (eg, colorectal carcinoma), gene analysis, variants in exon 2 (eg, codons 12 and 13) and exon 3 (eg, codon 61) |
| | 81313 | PCA3/KLK3 (prostate cancer antigen 3 [non-protein coding]/kallikrein-related peptidase 3 [prostate specific antigen]) ratio (eg, prostate cancer) |
| | 81314 | PDGFRA (platelet-derived growth factor receptor, alpha polypeptide) (eg, gastrointestinal stromal tumor [GIST]), gene analysis, targeted sequence analysis (eg, exons 12, 18) |
| | 81315 | PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative |
| | 81316 | ;single breakpoint (eg, intron 3, intron 6 or exon 6), qualitative or quantitative |
| | 81320 | PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F) |
| | 81327 | SEPT9 (Septin9) (eg, colorectal cancer) promoter methylation analysis |
| | 81334 | RUNX1 (runt related transcription factor 1) (eg, acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy), gene analysis, targeted sequence analysis (eg, exons 3-8) |
| | 81338 | MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; common variants (eg, W515A, W515K, W515L, W515R) |
| | 81339 | MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; sequence analysis, exon 10 |
| | 81340 | TRB@ (T cell antigen receptor, beta) (eg, leukemia and lymphoma), gene rearrangement analysis to detect abnormal clonal population(s); using amplification methodology (eg, polymerase chain reaction) |
| | 81341 | ;using direct probe methodology (eg, Southern blot) |
| | 81342 | TRG@ (T cell antigen receptor, gamma) (eg, leukemia and lymphoma), gene rearrangement analysis, evaluation to detect abnormal clonal population(s) |
| | 81345 | TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region) |

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| | 81347 | SF3B1 (splicing factor [3b] subunit B1) (eg, myelodysplastic syndrome/acute myeloid leukemia) gene analysis, common variants (eg, A672T, E622D, L833F, R625C, R625L) |
| | 81348 | SRSF2 (serine and arginine-rich splicing factor 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, P95H, P95L) |
| | 81351 | TP53 (tumor protein 53) (eg, Li-Fraumeni syndrome) gene analysis; full gene sequence |
| | 81352 | ;targeted sequence analysis (eg, 4 oncology) |
| | 81357 | U2AF1 (U2 small nuclear RNA auxiliary factor 1) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, S34F, S34Y, Q157R, Q157P) |
| | 81360 | ZRSR2 (zinc finger CCCH-type, RNA binding motif and serine/arginine-rich 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variant(s) (eg, E65fs, E122fs, R448fs) |
| | 81400 | Molecular pathology procedure, Level 1 |
| | 81401 | Molecular pathology procedure, Level 2 |
| | 81402 | Molecular pathology procedure, Level 3 |
| | 81403 | Molecular pathology procedure, Level 4 |
| | 81404 | Molecular pathology procedure, Level 5 |
| | 81405 | Molecular pathology procedure, Level 6 |
| | 81406 | Molecular pathology procedure, Level 7 |
| | 81407 | Molecular pathology procedure, Level 8 |
| | 81408 | Molecular pathology procedure, Level 9 |
| | 81445 | Solid organ neoplasm, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants and copy number variants or rearrangements, if performed; DNA analysis or combined DNA and RNA analysis |
| | 81449 | Solid organ neoplasm, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants and copy number variants or rearrangements, if performed; RNA analysis |
| | 81450 | Hematolymphoid neoplasm or disorder, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; DNA analysis or combined DNA and RNA analysis |
| | 81451 | Hematolymphoid neoplasm or disorder, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis |
| | 81455 | Solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes, genomic sequence analysis panel, interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; DNA analysis or combined DNA and RNA analysis |
| | 81456 | Solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes, genomic sequence analysis panel, interrogation for sequence variants and |

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| | copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis |
| 81457 | Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, microsatellite instability |
| 81458 | Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, copy number variants and microsatellite instability |
| 81459 | Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements |
| 81462 | Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants and rearrangements |
| 81463 | Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis, copy number variants, and microsatellite instability |
| 81464 | Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (eg, plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements |
| 81479 | Unlisted molecular pathology procedure |
| 81504 | Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores |
| 81518 | Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy |
| 81519 | Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes, utilizing formalin-fixed paraffin embedded tissue, algorithm reported as recurrence score |
| 81520 | Oncology (breast), mRNA gene expression profiling by hybrid capture of 58 genes (50 content and 8 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence risk score |
| 81521 | Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis |
| 81522 | Oncology (breast), mRNA, gene expression profiling by RT-PCR of 12 genes (8 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk score |
| 81523 | Oncology (breast), mRNA, next-generation sequencing gene expression profiling of 70 content genes and 31 housekeeping genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk to distant metastasis |

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| 81525 | Oncology (colon), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a recurrence score |
| 81528 | Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (KRAS mutations, promoter methylation of NDRG4 and BMP3) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result |
| 81529 | Oncology (cutaneous melanoma), mRNA, gene expression profiling by real-time RT-PCR of 31 genes (28 content and 3 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence risk, including likelihood of sentinel lymph node metastasis |
| 81538 | Oncology (lung), mass spectrometric 8-protein signature, including amyloid A, utilizing serum, prognostic and predictive algorithm reported as good versus poor overall survival |
| 81539 | Oncology (high-grade prostate cancer), biochemical assay of four proteins (Total PSA, Free PSA, Intact PSA, and human kallikrein-2 [hK2]), utilizing plasma or serum, prognostic algorithm reported as a probability score |
| 81540 | Oncology (tumor of unknown origin), mRNA, gene expression profiling by real-time RT-PCR of 92 genes (87 content and 5 housekeeping) to classify tumor into main cancer type and subtype, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a probability of a predicted main cancer type and subtype |
| 81541 | Oncology (prostate), MMA gene expression profiling by real-time RT-PCR of 46 genes (31 content and 15 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a disease-specific mortality risk score |
| 81542 | Oncology (prostate), mRNA, microarray gene expression profiling of 22 content genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as metastasis risk score |
| 81546 | Oncology (thyroid), mRNA, gene expression analysis of 10,196 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious) |
| 81551 | Oncology (prostate), promoter methylation profiling by real-time PCR of 3 genes (GSTP1, APC, RASSF1), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a likelihood of prostate cancer detection on repeat biopsy |
| 81552 | Oncology (uveal melanoma), mRNA, gene expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis |
| 81599 | Unlisted multianalyte assay with algorithmic analysis |
| 84999 | Unlisted chemistry procedure |
| 88271 | Molecular cytogenetics; DNA probe, each (eg, FISH) |
| 88273 | ;chromosomal in situ hybridization, analyze 10-30 cells (eg, for microdeletions) |
| 88274 | ;interphase in situ hybridization, analyze 25-99 cells |
| 88275 | ;interphase in situ hybridization, analyze 100-300 cells |

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| | 88291 | Cytogenetics and molecular cytogenetics, interpretation and report |
| **HCPCS** | G0327 | Colorectal cancer screening; blood-based biomarker |
| | S3854 | Gene expression profiling panel for use in the management of breast cancer treatment (Not valid for Medicare purposes)<br><br>**Note:** HCPCS code S3854 is not valid for use for Medicare Advantage members. CPT code 81519 should be used instead. |

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*