

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

Published: 04/01/2024

Next Review: 07/2024

Last Review: 03/2024

Medicare Link(s) Revised: 04/01/2024

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

Table 1: MoIDX Program and Medicare Jurisdictions

[Back to Criteria](#)

Medicare jurisdictions which have adopted the MoIDX Program are indicated below ([MoIDX site](#)). If the performing laboratory is not located in one of the marked states, MoIDX guidelines should not apply. Other Medicare guidance may be available.

STATE	MoIDX	STATE	MoIDX	STATE	MoIDX
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 3: Tests for Cancer Screening, Diagnosis, Prognosis, and Treatment

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
<p>4kscore® (81539) Bio Reference Laboratories Inc. (NJ)</p>	<p>4Kscore Test Algorithm (L37792) (<i>Applies to the indicated performing laboratory</i>) (<i>The companion article is A56653, which can be accessed directly from the LCD</i>)</p> <p>If performed in other locations/states, see these additional references:</p> <ul style="list-style-type: none"> • MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L38985) (<i>Laboratories in NC, SC, AL, GA, TN, VA, WV</i>) • MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39007) (<i>Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY</i>) • MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39005) (<i>Laboratories in CA, NV</i>) • Biomarker Testing (Prior to Initial Biopsy) for Prostate Cancer Diagnosis (L37733) (<i>Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT</i>) • MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39042) (<i>Laboratories in IA, KS, MO, NE, IN, MI</i>) • 4Kscore Test Algorithm (L37798) (<i>Laboratories in FL</i>) • MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L38997) (<i>Laboratories in KY and OH</i>)
<p>Abbott RealTime IDH1, IDH2, Abbott Molecular (81120, 81121)</p>	<p><i>Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:</i></p> <ul style="list-style-type: none"> • Billing and Coding: MolDX: Abbott RealTime IDH1 and IDH2 testing for Acute Myeloid Leukemia (AML) (A55712) <p><i>Laboratories in CA and NV:</i></p>

[Back to Criteria](#)

-
- Billing and Coding: MoIDX: Abbott RealTime IDH1 and IDH2 testing for Acute Myeloid Leukemia (AML) ([A55711](#))

NOTE: The above articles state: "This article reflects the FDA-approved indications on article creation date. MoIDX 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™ Assay (81546) Veracyte®

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

- MoIDX: Afirma™ Assay by Veracyte Billing and Coding Guidelines ([A54358](#))

Laboratories in CA and NV:

- MoIDX: Afirma™ Assay by Veracyte Billing and Coding Guidelines ([A54356](#))

Laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA:

- 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:

- MoIDX: Molecular Diagnostic Tests (MDT) [L36256](#) applies to genetic testing generally. (*Companion article A57527 can be accessed directly from the LCD.*)

Laboratories in CA and NV:

- MoIDX: Molecular Diagnostic Tests (MDT) [L35160](#) applies to genetic testing generally. (*Companion article A57526 can be accessed directly from the LCD.*)

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 MoIDX technology assessment are listed in the DEX™ registry. In addition, **clinical documentation must demonstrate how test results will be used** in the management or diagnosis of an illness or condition.

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)

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:

- MoIDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease ([L36186](#)) The companion articles A55600 and A57422 can be accessed directly from the LCD.

Laboratories in CA and NV:

- MoIDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease ([L36180](#)) The companion articles A55595 and A57421 can be accessed directly from the LCD.

Laboratories in AL, GA, TN, SC, VA, WV, NC:

- MoIDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease ([L36044](#)) The companion article A56959, can be accessed directly from the LCD.

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.

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 *MoIDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease* ([L36815](#)).

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:

- MoIDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease ([L36186](#))

Laboratories in CA and NV:

- MoIDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease ([L36180](#))

Laboratories in AL, GA, TN, SC, VA, WV, NC:

- MoIDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease ([L36044](#)) The companion article A56959 can be accessed directly from the LCD.

Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT:

- See specific genes listed in Molecular Pathology Procedures ([L35000](#))

Laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA:

- Biomarkers for Oncology ([L35396](#))

For MoIDX LCDs:

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.

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.”

***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**.

***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

See M-GT20 for the Xpresys Lung 2® and BDX-XL2 tests.

BluePrint® (81479) Agendia (CA)

MoIDX: BluePrint® Billing and Coding ([A55115](#)) (*Applies to the indicated performing laboratory*)

Bladder Tumor Marker (e.g., UroVysion, with or without FISH technology) (86294, 86316, 86386, 88120, 88121)

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

- Bladder/Urothelial Tumor Markers ([L36680](#)). Companion article A55029 can be accessed directly from the LCD.

Laboratories in CA and NV:

- Bladder/Urothelial Tumor Markers ([L36678](#)). Companion article A55028 can be accessed directly from the LCD.

BRAF Gene Tests

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

- Billing and Coding: MoIDX: FDA-Approved BRAF Tests ([A54420](#))

Laboratories in CA and NV:

- Billing and Coding: MoIDX: FDA-Approved BRAF Tests ([A54418](#))

NOTE: The articles above state: “This article reflects the FDA-approved indications on article creation date. MoIDX 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 BRCAAnalysis CDx and other panels limited to BRCA1 and BRCA2.

Note: This guidance applies only to testing to guide treatment selection (i.e., Lynparza, Talzenna, Rubraca). For testing for inherited cancer risk, see Cross References)

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

- Billing and Coding: MoIDX: Germline testing for use of PARP inhibitors ([A55295](#))

Laboratories in CA or NV:

- Billing and Coding: MoIDX: Germline testing for use of PARP inhibitors ([A55294](#))

Laboratories in FL:

- BRCA1 and BRCA2 Genetic Testing ([L36499](#)) (*Laboratories in FL*)

Breast Cancer IndexSM (aka BCI) (81518) bioTheranostics, Inc. (CA)

- MoIDX: Breast Cancer IndexTM (BCI) Gene Expression Test ([L37822](#))

CancerTypeID[®] (81479 or 81540) bioTheranostics, Inc. (CA)

- MoIDX: bioTheranostics Cancer TYPE ID[®] Billing and Coding Guidelines ([A54386](#)) (*Applies to the indicated performing laboratory*)

CGI Tissue of Origin[®] (formerly ResponseDX and Pathwork[®] Tissue of Origin) (81504) Cancer Genetics Inc. (CA)

- MoIDX: ResponseDX Tissue of Origin[®] Billing and Coding Guidelines ([A54494](#)) (*Applies to the indicated performing laboratory*)

clonoSEQ[®] (0364U, 81479) Adaptive Biotechnologies

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, UT, WY:

- MoIDX: Minimal Residual Disease Testing for Cancer ([L38816](#)).

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 A58456 can be accessed directly from the LCD.

Colorectal Screening Tests (CPT coding varies, but may include 0002U, 0091U, 81479, 81528, G0327)

Examples:

- BeScreened-CRC (0163U) (Beacon Biomedical and Sonora Quest Laboratory)
- Cologuard™ Colorectal Screening (81528) Exact Sciences Laboratories
- ColoSense (0421U) Geneoscopy
- Colonsentry® (81479) Innovative Diagnostic Laboratory (VA)
- FirstSight^{CRC} (0091U) (CA)
- Epi proColon (G0327)
- PolypDX™ (0002U)

NCD for Colorectal Cancer Screening Tests ([210.3](#)) 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™). Of note, while Epi proColon is a blood-based test, 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 regarding sensitivity and specificity, and thus, is non-covered at this time.

Additional Notes:

- In addition to the NCD 210.3, both the BeScreened-CRC and ColonSentry® tests are not medically necessary 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..." These tests are "pre-screening" screening tests, performed in the absence of signs and symptoms. Therefore, they are not medically necessary based on the Medicare Benefit and medical necessity requirements.

Colvera (0229U) Colvera Lab (NJ)

Billing and Coding: Biomarkers for Oncology ([A52986](#)). (Applies to the indicated performing laboratory)

COMPASS® Bone Marrow Evaluation
(81479) Genoptix (CA)

This test is not currently found in the DEX™ Change Healthcare Registry website, indicating a TA has not yet 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 MoIDX but determined to not meet Medicare's requirements for coverage. Therefore, this test is considered not medically reasonable or necessary according to the Palmetto GBA MoIDX Program and the Social Security Act, §1862(a)(1)(A).

ConfirmMDx™ (81551) MDxHealth (CA)

MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer ([L39005](#)). (The companion article A58718 can be accessed directly from the LCD).

Note: This LCD/article combo also addresses Progensa PCA3 testing (CPT 81313) with versions for all MoIDX areas.

Decipher Bladder TURBT® (0016M)
Decipher Biosciences (CA)

MoIDX: Molecular Diagnostic Tests (MDT) ([L35160](#)). According to the DEX™ Change Healthcare Registry website, this test is listed as a potentially covered test by MoIDX for Medicare.

Decipher® Prostate Cancer Classifier Assay (Decipher Biopsy and Decipher Post-Op) (81542, 81479) GenomeDX or Decipher Biosciences (CA)

MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease ([L38339](#)) (The companion article A57372 can be accessed directly from the LCD.)

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):

- MolDX: Melanoma Risk Stratification Molecular Testing ([L37748](#)). (The companion article A57290 can be accessed directly from the LCD). The DecisionDx-Melanoma assay is listed in the Dex registry as “covered.”

For **DecisionDx DiffDx-Melanoma** (0314U):

- MolDX: Melanoma Risk Stratification Molecular Testing ([L37748](#)). (The companion article A57290 can be accessed directly from the LCD). The DecisionDx DiffDx-Melanoma assay is listed in the Dex registry as “covered.”

For **DecisionDx-SCC** (0315U):

- The DecisionDx-SCC test by Castle Biosciences is in the Dex registry listed as “not covered”, therefore not medically necessary, according to [L36256](#).

For **DecisionDx-UM (Uveal melanoma)** (81552, 84999, 0081U):

- MolDX: DecisionDx-UM (Uveal Melanoma) ([L37072](#)) (Applies to the indicated performing laboratory)

DetermaRx™ (0288U) Oncocyte Corporation (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:

- Billing and Coding: MolDX: FDA-Approved EGFR Tests ([A54424](#))

Laboratories in CA and NV:

- Billing and Coding: MolDX: FDA-Approved EGFR Tests ([A54422](#))

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)

MoIDX: EndoPredict® Breast Cancer Gene Expression Test ([L37311](#)) (Applies to the indicated performing laboratory) (Companion article A57608 can be accessed directly from the LCD.)

Envisage (0386U) and **Esopredict** (0398U) Capsulomics/Previs (MD)

Biomarkers for Oncology ([L35396](#)) (Applies to the indicated performing laboratory)

ExoDx™ Prostate (0005U) Exosome Diagnostics (MA)

Biomarker Testing for Prostate Cancer Diagnosis ([L37733](#)) (Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT) (Companion article A56609 can be accessed directly from the LCD.)

FGFR3 Gene Tests for Bladder Cancer (coding varies)

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

- MoIDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer ([L38649](#)) (Companion article can be accessed directly from the LCD.)

Laboratories in CA and NV:

- MoIDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer ([L38647](#)) (Companion article can be accessed directly from the LCD.)

Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT:

- Molecular Pathology Procedures ([L35000](#)) (Published by National Government Services) (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)

Laboratories in CO, NM, OK, TX, AK, LA, MS, DE, MD, PA, NJ:

- Biomarkers for Oncology ([L35396](#))

NOTE: FDA-approved companion diagnostic tests (e.g., theascreen® 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)

MoIDX: 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:

- MoIDX: Molecular Diagnostic Tests (MDT) [L36256](#) applies to genetic testing generally. (Companion article A57527 can be accessed directly from the LCD.)

Laboratories in CA and NV:

- MoIDX: Molecular Diagnostic Tests (MDT) [L35160](#) applies to genetic testing generally. (Companion article A57526 can be accessed directly from the LCD.)

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 MoIDX technology assessment are listed in the DEX™ registry. In addition, **clinical documentation must demonstrate how test results will be used** in the management or diagnosis of an illness or condition.

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 MoIDX for Medicare (listed as FoundationOne® Heme-Hematologic Malignancies and Sarcomas; Test ID: Test_5684).

For myeloid malignancies (including suspected malignancies), the following is applicable:

- MoIDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies ([L38047](#)) (Use for laboratories in either NC or MA)

For sarcoma or other solid tumor testing using **blood samples**, the following is applicable:

- MoIDX: Plasma-Based Genomic Profiling in Solid Tumors ([L38043](#)) (Use for laboratories in either NC or MA)

For sarcoma or other solid tumor testing using **tumor samples**, the following is applicable:

- MoIDX: Next-Generation Sequencing for Solid Tumors ([L38045](#)) (Use for laboratories in either NC or MA)

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..." This test is a cancer screening test performed in the absence of signs and symptoms, and it is listed in the DEX™ Change Healthcare Registry as "not covered" Therefore, it is considered **not medically necessary**.

GeneTrails® Heme Fusion Gene Panel (81456, 81479) OHSU Knight Diagnostics Laboratories (OR)

- MoIDX: 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". Therefore, this test is considered **not medically reasonable and necessary**.*

GeneTrails® Comprehensive Solid Tumor Panel (124 genes) (81445, 81479) and

- MoIDX: Next-Generation Sequencing for Solid Tumors ([L38121](#))

GeneTrails® Solid Tumor Fusion Gene Panel (20 genes) (81445, 81479) OHSU Knight Diagnostics Laboratories (OR)

Guardant360® Panel (83 genes) (0326U) and **Guardant360® LDT** Guardant Health (CA)

- MoIDX: Plasma-Based Genomic Profiling in Solid Tumors ([L39230](#)) *Companion article A57867 can be accessed directly from the LCD.*

Note: For the **Guardant360® CDx** test, see the row for "Next Generation Sequencing Panel Tests Subject to the Medicare NCD 90.2" below.

The Guardant360® 83-gene panel is listed in the DEX™ Change Healthcare Registry website, as a test that has completed a TA by MoIDX and has a "covered" designation.

*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™** (81479) Guardant Health (CA)

MoIDX: Minimal Residual Disease Testing for Cancer ([L38814](#)). Companion article A58456 can be accessed directly from the LCD.

- The Guardant360 Response™ is addressed in this LCD/article with coverage.
- The Guardant Reveal™ test is listed in the DEX™ Change Healthcare Registry as "**not covered**."

HER2 (ERBB2) Testing (includes DEPAarray™ HER2, CellSearch® HER2

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

Circulating Tumor Cell) (0009U, 0338U, 81479))

- MoIDX: Molecular Diagnostic Tests (MDT) ([L36256](#)) *Companion article A57527 can be accessed directly from the LCD.*

Laboratories in CA and NV:

- MoIDX: Molecular Diagnostic Tests (MDT) ([L35160](#)) *Companion article A57526 can be accessed directly from the LCD.*

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 MoIDX technology assessment are listed in the DEX™ registry. In addition, **clinical documentation must demonstrate how test results will be used** in the management or diagnosis of an illness or condition.

Laboratories in CO, NM, OK, TX, AK, LA, MS, DE, MD, PA, NJ

- Biomarkers for Oncology ([L35396](#))

IDH1/IDH2 Gene Tests (81120, 81121)

See entry for “Abbott RealTime IDH2” testing above for that test.

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

- MoIDX: Molecular Diagnostic Tests (MDT) ([L36256](#)) *Companion article A57527 can be accessed directly from the LCD.*

Laboratories in CA and NV:

- MoIDX: Molecular Diagnostic Tests (MDT) ([L35160](#)) *Companion article A57526 can be accessed directly from the LCD.*

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 MoIDX technology assessment are listed in the DEX™ 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) HaliDx or Veracyte (VA)

MoIDX: 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 MoIDX review. This test 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 or necessary** according to the Palmetto GBA MoIDX Program and the Social Security Act, §1862(a)(1)(A).

InvisionFirst™ - Lung (aka *InVision*)
(0388U, 81479) Inivata (NC)

MoIDX: 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:

- MoIDX: FDA-Approved KRAS Tests ([A54500](#))

Laboratories in CA and NV:

- MoIDX: FDA-Approved KRAS Tests ([A54498](#))

NOTE: This guidance states: “This article reflects the FDA-approved indications on article creation date. MoIDX 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 \(In Vitro and Imaging Tools\)](#).

LungLB® (0317U) LungLife AI® (CA)

MoIDX: Phenotypic Biomarker Detection from Circulating Tumor Cells ([L38643](#)). This test 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 or necessary**.

Lymph2Cx (0017M) and **Lymph3Cx**
Lymphoma Molecular Subtyping
Assay (0120U) Mayo Clinic Laboratory
(AZ, MN, FL)

Laboratory in Arizona:

- The MoIDX 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*)
- 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).

Laboratory in Minnesota:

- 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.

Laboratory in Florida:

- The LCD for *Molecular Pathology Procedures* ([L34519](#)) includes the same note as that mentioned above.

MammaPrint® (81521) Agendia (CA)

MoIDX: MammaPrint Billing and Coding Guidelines ([A54445](#))

MGMT Gene Promoter Tests (81287)

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

- MoIDX: MGMT Promoter Methylation Analysis ([L36192](#)) *Companion article A57433 can be accessed directly from the LCD.*

Laboratories in CA and NV:

- MoIDX: 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.*)

MI TumorSeek (81479) Caris Life Science (AZ)

MoIDX: Next-Generation Sequencing for Solid Tumors ([L38121](#))

*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 MoIDX 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)

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:

- MoIDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker Billing and Coding Guidelines for Patients with Unresectable or Metastatic Solid Tumors ([A56104](#))

Laboratories in CA and NV:

- MoIDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker Billing and Coding Guidelines for Patients with Unresectable or Metastatic Solid Tumors ([A56103](#))

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:

- MoIDX: 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:

- MoIDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer ([L39007](#)). *Companion article A58724 can be accessed directly from the LCD.*

Myelodysplastic Syndrome (MDS) Diagnosis Panels (any NGS panel to diagnose MDS, with or without FISH testing)

MoIDX: 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 accessed directly from the LCD.*

myPath Melanoma Assay (81479, 0090U) Myriad Genetics (UT)

For services after 8/6/2023:

- MoIDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma ([L39375](#)). *Companion article A59181 can be accessed directly from the LCD.*

For services prior to 8/6/2023:

- MoIDX: myPath Melanoma Assay ([L37881](#)) (Companion article A57627 can be accessed directly from the LCD.)

NGS Panel Tests Subject to the Medicare NCD 90.2

For tests **with** FDA-approval or clearance as an approved companion diagnostic or in vitro test, when used for the approved indication (cancer type):

- **Agilent Resolution ctDx FIRST** (0397U) Agilent
- **BRACAnalysis CDx** (81162) Myriad Genetics
- **FoundationOne CDx™** (F1CDx) (0037U) Foundation Medicine
- **FoundationOne® Liquid CDx** (0239U) Foundation Medicine

- Next Generation Sequencing (NGS) ([90.2](#))

*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 NCD is **not applicable** 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).*

Additional Information:

- **Guardant360® CDx** (0242U) Guardant Health
- **MSK-IMPACT™** (0048U) Memorial Sloan Kettering Cancer Center
- **MyChoice® CDx** (0172U) Myriad Genetics
- **Oncomine™ Dx Target Test** (0022U) Thermo Fisher Scientific
- **OncoReveal™ Lung and Colon Cancer** (0448U) Pillar Biosciences
- **Praxis™ Extended RAS Panel** (0111U) Illumina, Inc.

Note: This NCD only addresses NGS testing to detect genomic variants.

- 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.”
- 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.
- 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 (tumor tissue) testing should only be reviewed under the “Somatic (Acquired) Cancer” section.

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:

- MoIDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies ([L38125](#))

For laboratories in CA, NV:

- MoIDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies ([L38123](#))

For laboratories in NC, SC, AL, GA, VA, WV:

- MoIDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies ([L38047](#))

NGS Panel Tests for Solid Tumors (not FDA-approved or cleared as companion diagnostic tests for the cancer indication)

For laboratories in NC, SC, AL, GA, VA, WV:

- MoIDX: Next-Generation Sequencing for Solid Tumors ([L38045](#))

For laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

- MoIDX: Next-Generation Sequencing for Solid Tumors ([L38121](#))

For laboratories in CA, NV:

- MoIDX: Next-Generation Sequencing for Solid Tumors ([L38119](#))

Note: This is for tumor tissue testing. For plasma-based [liquid biopsy]

genomic profiling panel tests, see applicable row below)

According to the DEX™ Change Healthcare Registry website, the following tests are noted as **potentially covered** tests by MoIDX when above LCD medical necessity criteria are met:

- ✓ Guardant360 TissueNext (0334U), Guardant Health (CA)
- ✓ Solid Tumor Expanded Panel (0379U), Quest Diagnostics
- ✓ Strata Select (0391U) and StrataNGS, Strata Oncology, Inc.

Laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA:

- Biomarkers for Oncology ([L35396](#))

Nodify CDT (0360U) Biodesix (CO and KS)

For laboratory in KS:

- MoIDX: Molecular Diagnostic Tests ([L36807](#)) states reimbursement is only allowed for “approved tests... for dates of service consistent with the effective date of the coverage determination” after MoIDX review. According to the DEX™ Change Healthcare Registry website, this test is listed as a test that is “**not covered**” by MoIDX for Medicare.

For laboratory in CO:

- LCD Biomarkers for Oncology ([L35396](#)) and companion article A52986. According to the DEX™ Change Healthcare Registry website, this test is listed as a test that is “not covered” by MoIDX for Medicare, indicating that it has not demonstrated clinical validity/utility and does not meet the LCD criteria, and is therefore considered **not medically reasonable and necessary**.

NRAS Gene Tests (81311, 81479)

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

- MoIDX: NRAS Genetic Testing ([L36339](#)) *Companion article A57487 can be accessed directly from the LCD.*

Laboratories in CA and NV:

- MoIDX: 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:

According to the MoIDX 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.”

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.

Omnipathology Oropharyngeal HPV PCR Test (0429U) Omnipathology (CA)

Unless specifically covered in this NCD, any other NCD, by statute or regulation, preventive services are non-covered by Medicare.

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) Genomic Health (CA)

MoIDX: Phenotypic Biomarker Detection from Circulating Tumor Cells ([L38643](#)) *Companion article A58183 can be accessed directly from the LCD.*

Note: This LCD/article combo 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:

- MoIDX: Oncotype DX® Breast Cancer Assay Billing and Coding Guidelines ([A54480](#))

Laboratory in WI:

- 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)

MoIDX: 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:

- MoIDX: Oncotype DX® Colon Cancer Coding and Billing Guidelines ([A54484](#))

Laboratory in WI:

- Billing and Coding: Molecular Pathology Procedures ([A56199](#)) *The coverage policy L35000 can be accessed directly from the article,*

Oncotype DX® Genomic Prostate Score (aka, Oncotype DX® Prostate Cancer Assay) (0047U) MDxhealth (CA)

MoIDX: 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)

Per the manufacturer, "The results help to determine if men with an elevated prostate specific antigen and/or abnormal digital rectal exam may need additional studies or workup." This test itself doesn't make treatment or diagnosis decisions but is used to determine if MORE testing is required. This does not meet the LCD [L34519](#) requirement that testing is directly involved in treatment and management of a condition, nor would it meet Medicare's medically necessary definition under *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..."

PathFinderTG®, RedPath Integrated Pathology, PA (81479)

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)

MoIDX: Percepta® Bronchial Genomic Classifier ([L36886](#)) (*Applies to the indicated performing laboratory*) *Companion article A57502 can be accessed directly from the LCD.*

Pervenio™ Lung NGS (25 genes) (81479) Life Technologies™ (CA)

MoIDX: Next-Generation Sequencing for Solid Tumors ([L38119](#))

According to the DEX™ Change Healthcare Registry website, this test is listed as **not covered**.

Pigmented Lesion Assay (PLA) (0089U) DermTech (CA)

MoIDX: 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:

- Billing and Coding: MoIDX: PIK3CA Gene Tests ([A55602](#))

Laboratories in CA and NV:

- Billing and Coding: MoIDX: PIK3CA Gene Tests ([A55597](#))

NOTE: Certain tests, such as the theascreen® 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)

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:

- MoIDX: Plasma-Based Genomic Profiling in Solid Tumors ([L39230](#)) Companion article A58973 can be accessed directly from the LCD.

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, and WY:

- MoIDX: Plasma-Based Genomic Profiling in Solid Tumors ([L39232](#)) Companion article A58975 can be accessed directly from the LCD.

Laboratories in IA, KS, MO, NE, IN, and MI:

- MoIDX: Plasma-Based Genomic Profiling in Solid Tumors ([L38168](#)) Companion article A57936 can be accessed directly from the LCD.

Laboratories in NC, SC, AL, GA, VA, TN, and WV:

- MoIDX: Plasma-Based Genomic Profiling in Solid Tumors ([L38043](#)) Companion article A57867 can be accessed directly from the LCD.

Laboratories in OH and KY:

- MoIDX: Plasma-Based Genomic Profiling in Solid Tumors ([L38065](#)) Companion article A57917 can be accessed directly from the LCD.

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 MoIDX 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.*

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 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:

- MolDX: Breast Cancer Assay: Prosigna ([L36386](#)) *Companion article A57364 can be accessed directly from the LCD.*

Laboratories in NC, SC, VA, WV, AL, TN, or GA, and LabCorp, regardless of state rendered:

- MolDX: Breast Cancer Assay: Prosigna ([L36125](#)) *Companion article A56949 can be accessed directly from the LCD.*

Laboratories in CA and NV:

- MolDX: Breast Cancer Assay: Prosigna ([L36380](#)) *Companion article A57363 can be accessed directly from the LCD.*

SelectMDx (0339U) MDxHealth (CA, TX)

For laboratory in CA:

- MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer ([L39005](#)) *Companion article A58718 can be accessed directly from the LCD. According to the DEX™ Change Healthcare Registry website, this test is listed as a **covered** test by MolDX for Medicare.*

For laboratory in TX:

- Biomarkers for Oncology ([L35396](#)) and companion article A52986. According to the DEX™ Change Healthcare Registry website, this test is listed as a **covered** test.

SEPT9 Gene Tests (81327)

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

- Billing and Coding: MoIDX: SEPT9 Gene Test ([A55628](#))

Laboratories in CA and NV:

- Billing and Coding: MoIDX: SEPT9 Gene Test ([A55623](#))

Signatera™ (0340U) Natera (CA, TX)

For laboratory in CA:

- MoIDX: Minimal Residual Disease Testing for Solid Tumor Cancers ([L38814](#)) and companion article [A58454](#). According to the DEX™ Change Healthcare Registry website, this test is listed as a **covered** test.

For laboratory in TX:

- 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 MoIDX for Medicare, indicating that it has demonstrated clinical validity/utility.

ThyGenX (81445), **ThyGeNEXT** (0245U), and **ThyraMIR** (0018U, 81479) Interpace Diagnostics

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

TissueCypher® Barrett's Esophagus Assay (0108U) Cernostics/Castle Biosciences (PA)

Biomarkers for Oncology ([L35396](#)) (Applies to the indicated performing laboratory)

Xpresys Lung® and Xpresys Lung 2® (XL2, or BDX-XL2) (81599, 0080U)
Integrated Diagnostics (WA)

Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:

- MoIDX: Xpresys Lung ([L37062](#)) Companion article A5735 can be accessed directly from the LCD. Coverage outlined in this LCD is limited to only XL2.

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**.

Additional Tests That Are Not Covered

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

Dawn IO Melanoma (0357U) Intervenn
(CA)

DCISionRT® (0295U) PreludeDx™
(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)

MyProstateScore 2.0 (0403U) LynxDx

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

Resolution ctDx Lung (0179U)
Agilent/Resolution Biosciences (WA)

Reveal Lung Nodule Characterization
(0092U) MagArray, Inc. (CA)

The MoIDX Program requires labs to submit a technology assessment (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 MoIDX review. The results of these TAs are published on the DEX™ Registry, 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**.

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 MoIDX review. According to the DEX™ Change Healthcare Registry website, this test is listed as a **non-covered** test by MoIDX for Medicare.

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** under LCD L35396 and *Title XVIII of the Social Security Act, Section 1862(a)(1)(A)*.

BBDRisk Dx™ (0067U) Silbiotech (MD)

LC-MS/MS Targeted Proteomic Assay, (0174U) OncoOmicDx/mProbe

CxBladder Triage, Detect, Detect+, and Monitor (0363U, 0420U, 0012M, 0013M) Pacific Edge Diagnostics (PA)

- Biomarkers for Oncology ([L35396](#))

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 reasonable or necessary.

For the CxBladder tests, the Revision History Information from 10/4/2018 reads, “Non-coverage reaffirmed for CPT codes 0012M and 0013M for CxBladder.” Another entry dated 02/01/2017 reads, “After review of the submitted literature it has been determined that non-coverage of CxBladder will remain.” Therefore, this test is considered **not medically necessary**.

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 (MoIDX)

The Medicare Molecular Diagnostic Services Program (MoIDX) 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 MoIDX guidelines provide assessments and indicate coverage or non-coverage of the test.^[12-15]

The MoIDX program will affect diagnostic services reported with the following CPT/HCPCS codes:⁽¹³⁾

Code Category/Description	2018 MoIdx Code Range
Tier 1	81161-81383
Tier 2	81400-81408
Genomic Sequencing Procedures	81410-81471
Molecular Multianalyte Assays (MAAA)	81490-81595
MAAA Admin. Codes	MAAA codes for molecular tests only
Immunology	86152-86153
PLA	PLA codes for molecular tests only
Cytology	88120-88121
The following NOC codes are in scope for molecular tests only	81479, 81599, 84999, 85999, 86849, 87999

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 MoIDX 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 MoIDX Program](#)
12. Noridian Healthcare Solutions - [Palmetto GBA MoIDX 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 comprehensive genomic profile (CGP) testing, see the Noridian, *Billing and Coding: MolDX: Targeted and Comprehensive Genomic Profile Next-Generation Sequencing Testing in Cancer* ([A56518](#)) for 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
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
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
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 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	Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score
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
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
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
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
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 formalin-fixed 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
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-gammaprothrombin (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, 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, algorithm reported as a probability of bladder cancer
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, formalin-fixed 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, splice site 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
0403U	Oncology (prostate), mRNA, gene expression profiling of 18 genes, first-catch post-digital rectal examination urine (or processed 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 paraffinembedded (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 (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
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

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)
81162	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis (ie, detection of large gene rearrangements)
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) <u>(eg, solid tumors) translocation analysis</u>
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
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)
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)
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 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
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
	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)
		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.