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Medicare Advantage Policy Manual **Policy ID:** M-GT83

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

Published: 07/01/2026

Next Review: 02/2027

Last Review: 06/2026

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

DESCRIPTION

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

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

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

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

MEDICARE ADVANTAGE POLICY CRITERIA

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

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

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

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

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

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

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

Table 1: MolDX Program and Medicare Jurisdictions

Back to Criteria

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

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

Table 2: Tests for Cancer Screening, Diagnosis, Prognosis, and Treatment

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 **For Medicare Coverage Determinations and Articles, see the** *Medicare Coverage Database*	Back to Criteria
4kscore® *(81539)* Bio Reference Laboratories Inc. (NJ)	4Kscore Test Algorithm (L37792) and companion article A56653 If performed in other locations/states, see these additional references: • MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L38985) *(Laboratories in NC, SC, AL, GA, TN, VA, WV)* • MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39005) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV)*	

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE **For Medicare Coverage Determinations and Articles, see the** *Medicare Coverage Database* Back to Criteria
	• Billing and Coding: Biomarker Testing for Prostate Cancer Diagnosis (A56609) *(Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT)* • MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39042) *(Laboratories in IA, KS, MO, NE, IN, MI)* • 4Kscore Test Algorithm (L37798) *(Laboratories in FL)* • MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L38997) *(Laboratories in KY and OH)*
Abbott RealTime IDH1, IDH2, Abbott Molecular *(81120, 81121)*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Molecular Diagnostic Tests (MDT) (L35160) and Billing and Coding: MolDX: Abbott RealTime IDH1 and IDH2 testing for Acute Myeloid Leukemia (AML) (A55711) The article states that "MolDX will allow future FDA approved and amended indications for these tests." To view FDA-approved IDH1 and IDH2 tests and their corresponding medications, see the FDA List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools))
Afirma™ GSC *(81546)* Veracyte®	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Molecular Testing for Risk Stratification of Thyroid Nodules (L39682) and companion article A59509 The MolDX Program requires that tests complete a TA for analytical and clinical validity, and clinical utility. The Afirma™ GSC (81546) has completed a TA and is listed in the DEX™ Change Healthcare Registry as "covered." *Laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA:* • Biomarkers for Oncology (L35396) and companion article A52986 Use the LCD guidance specific to Afirma™ and coding and frequency allowance guidance in the article.
ALK Gene Tests	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Molecular Diagnostic Tests (MDT) (L35160) and companion article A57526 Some FDA-approved medications have companion diagnostics tests for ALK rearrangements (see List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools).

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE **For Medicare Coverage Determinations and Articles, see the** *Medicare Coverage Database* Back to Criteria
BCR-ABL Gene Tests (non-NGS) *(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, CA, NV:* • MolDX: Non-Next Generation Sequencing Tests for the Diagnosis of BCR-ABL Negative Myeloproliferative Neoplasms (L39923) and companion article A55595 *Laboratories in AL, GA, TN, SC, VA, WV, NC:* • MolDX: Non-Next Generation Sequencing Tests for the Diagnosis of BCR-ABL Negative Myeloproliferative Neoplasms (L39919) and companion article A53531 Testing for BCR-ABL is considered "step one" in the LCDs and may be considered medically necessary for these indications.
BCR-ABL Negative Myeloproliferative Disease Testing (non-NGS) *(includes JAK2, CALR, MPL gene testing) (81479)*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Non-Next Generation Sequencing Tests for the Diagnosis of BCR-ABL Negative Myeloproliferative Neoplasms (L39923) and companion article A59835. *Laboratories in AL, GA, TN, SC, VA, WV, NC:* • MolDX: Non-Next Generation Sequencing Tests for the Diagnosis of BCR-ABL Negative Myeloproliferative Neoplasms (L39919) *and companion article.* *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)
BDX-XL2 (Xpresys Lung® and Xpresys Lung 2®) *(81599, 0080U)* Biodesix (previously Integrated Diagnostics)	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • BDX-XL2 (L37054) and companion article A57356 *Laboratory in KS:* • BDX-XL2 (L37216) and companion article A57558 The clinical utility for the earlier version of Xpresys Lung® is not noted as demonstrated in the same way XL2 has been demonstrated and is therefore considered **not medically necessary**.
BluePrint® *(0630U)* Agendia (CA)	MolDX: BluePrint® Billing and Coding (A55115)
Bladder Tumor Marker *(e.g., UroVysion, with or without FISH technology)*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY:*

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE For Medicare Coverage Determinations and Articles, see the *Medicare Coverage Database* Back to Criteria
(0465U, 0549U, 86294, 86316, 86386, 88120, 88121)	• Bladder/Urothelial Tumor Markers (L36678) and companion article A55028 *Laboratories in CA and NV:* • Bladder/Urothelial Tumor Markers (L36678) and companion article A55028 *Laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA:* • Genetic Testing in Oncology: Specific Tests (L39365) and companion article A59125
BRAF Gene Tests	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Molecular Diagnostic Tests (MDT) (L35160) and companion article A54418 The article states that, "MolDX will allow future FDA approved and amended indications for these tests." To view FDA-approved *BRAF* tests and their corresponding medications, see the FDA List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools)
BRCA1 and BRCA2 Testing for Treatment Selection *(Includes BRACAnalysis CDx, other BRCA1 and BRCA2 panels.* ***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, CA, NV:* • MolDX: Molecular Diagnostic Tests (MDT) (L35160) and companion article A55294 *Laboratories in FL:* • BRCA1 and BRCA2 Genetic Testing (L36499)
Breast Cancer Index℠ *(aka BCI) (81518)* bioTheranostics, Inc. (CA)	• MolDX: Breast Cancer IndexTM (BCI) Gene Expression Test (L37822) and companion article A57773
CancerTypeID® *(81479 or 81540)* bioTheranostics, Inc. (CA)	• MolDX: Molecular Diagnostic Tests (MDT) (L35160) and companion article A54386
clonoSEQ® *(0364U, 81479)* Adaptive Biotechnologies	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, UT, WY, CA, NV:* • MolDX: Minimal Residual Disease Testing for Cancer (L38814) and companion article A58996.

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE For Medicare Coverage Determinations and Articles, see the *Medicare Coverage Database* Back to Criteria
	Article has specific information about the clonoSEQ® test coverage.
Colorectal Screening Tests *(CPT coding varies)* *Examples:* • BeScreened-CRC (0163U) (Beacon Biomedical and Sonora Quest Laboratory) • Cologuard™ Colorectal Screening (81528) Exact Sciences Laboratories • Cologuard Plus™ (0464U) Exact Sciences Laboratories (*see adjacent Note addressing this test*) • ColoSense (0421U) Geneoscopy • Colonsentry® (81479) Innovative Diagnostic Laboratory (VA) • Epi proColon (G0327) • FirstSight^{CRC} (0091U) (CA) • Guardant Shield (0537U) (CA) • 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™). See Medicare Preventive Services: Colorectal Cancer Screening for additional information and coding. Coverage of blood-based biomarker screening tests requires FDA approval or marketing clearance. Tests such as the BeScreened-CRC and ColonSentry® that do not have this clearance are **not covered**. In addition, tests must meet performance characteristic thresholds. The Epi proColon is an FDA-cleared blood-based test, but according to the Decision Memo for Screening for Colorectal Cancer - Blood-Based Biomarker Tests (CAG-00454N), this test does not meet the Medicare criteria for an appropriate blood-based biomarker CRC screening test, as it does not meet test performance characteristic requirements and thus, is not covered.
Colvera *(0229U)* Colvera Lab (NJ)	Genetic Testing in Oncology: Specific Tests (L39365) and companion article A59125
COMPASS® Bone Marrow Evaluation *(81479)* Neogenomics/Genoptix (CA)	This test is not listed in the DEX™ Change Healthcare Registry website, indicating a TA has not been completed. Therefore, this test is considered **not medically reasonable or necessary** according to the Palmetto GBA MolDX Program and the Social Security Act, §1862(a)(1)(A).
ConfirmMDx™ *(81551)* MDxHealth (CA)	MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39005) and companion article A58718 This guidance also addresses Progensa *PCA3* testing (CPT 81313).
Decipher Bladder TURBT® *(0016M)* Decipher Biosciences (CA)	MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer (L38647) and companion article A58181 This test has completed a MolDX TA and is listed in the DEX™ Change Healthcare Registry website as “covered.”

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE **For Medicare Coverage Determinations and Articles, see the** *Medicare Coverage Database* Back to Criteria
Decipher® Prostate Cancer Classifier Assay *(Decipher Biopsy and Decipher Post-Op) (81542, 81479)* GenomeDX or Decipher Biosciences (CA)	For localized prostate cancer: • MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease (L38339) and companion article A57372 For castration-resistant and metastatic prostate cancer: • MolDX: Gene Expression Profile Tests for Decision-Making in Castration Resistant and Metastatic Prostate Cancers (L39686) and companion article A59513 The Decipher Biopsy and the Decipher Post-Op are both marketed under the name Decipher® Prostate Cancer Classifier Assay, and the LCDs apply to both versions.
DecisionDx Tests, Castle Biosciences Inc. (AZ)	For ***DecisionDx-Melanoma*** *(81599):* • MolDX: Melanoma Risk Stratification Molecular Testing (L37750) and companion article A57268 This test has completed a MolDX TA and is listed in the DEXTM Change Healthcare Registry website as "covered." For ***DecisionDx DiffDx-Melanoma*** *(0314U):* • MolDX: Melanoma Risk Stratification Molecular Testing (L37750) and companion article A57268 This test has completed a MolDX TA and is listed in the DEX™ Change Healthcare Registry website as "covered." For ***DecisionDx-SCC*** *(0315U):* • MolDX: Molecular Biomarker Testing for Risk Stratification of Cutaneous Squamous Cell Carcinoma (L39589) and companion article A59386 *(for laboratories in CA)* • Genetic Testing in Oncology: Specific Tests (L39365) *(for laboratories in PA)* For ***DecisionDx-UM (uveal melanoma)*** *(81552, 84999, 0081U)*: • MolDX: DecisionDx-UM (Uveal Melanoma) (L37070) and companion article A57621
EGFR Gene Tests *(81235)*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Molecular Diagnostic Tests (MDT) (L35160) and companion article A54422 The article states, "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

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE For Medicare Coverage Determinations and Articles, see the *Medicare Coverage Database* Back to Criteria
	List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools))
EndoPredict® Breast Cancer Gene Expression Test *(81599, 81518, 81522)* Myriad Genetics (UT)	MolDX: EndoPredict® Breast Cancer Gene Expression Test (L37295) and companion article A57607
ExoDx™ Prostate *(0005U)* Exosome Diagnostics (MA)	Billing and Coding: Biomarker Testing for Prostate Cancer Diagnosis (A56609)
FGFR3 Gene Tests for Bladder Cancer *(coding varies)*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer (L38647) and companion article A58181 *Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT:* • Molecular Pathology Procedures (L35000) and companion article A56199. See the *FGFR3*-specific guidance in the LCD and article, including the note for *FGFR3* testing. *Laboratories in CO, NM, OK, TX, AK, LA, MS, DE, MD, PA, NJ:* • Biomarkers for Oncology (L35396) FDA-approved companion diagnostic tests (e.g., therascreen® FGFR RGQ PCR Kit) may be considered **medically necessary** for the indication(s) noted on the FDA approval list (see the FDA List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools).
FISH *(fluorescent in situ hybridization)* **for myelodysplastic syndromes** *(88271, 88273, 88274, 88275, 88291)*	MolDX: MDS FISH (L37620) and companion article A56913 According to the LCD, "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."
FLT3 Gene Tests *(coding varies)*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Molecular Diagnostic Tests (MDT) L35160 and companion article A57526 FDA-approved companion diagnostic tests for *FLT3* may be considered **medically necessary** 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).
FoundationOne® Heme *(405 genes) (81479)*	For myeloid malignancies (including suspected malignancies):

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE **For Medicare Coverage Determinations and Articles, see the** *Medicare Coverage Database* Back to Criteria
Foundation Medicine, Inc. (MA or NC)	• MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38047) *(for laboratories in either NC or MA)* For sarcoma or other solid tumor testing using blood samples: • MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L38043) *(for laboratories in either NC or MA)* For sarcoma or other solid tumor testing using tumor samples: • MolDX: Next-Generation Sequencing for Solid Tumors (L38045) *(for laboratories in either NC or MA)* This test has completed a MolDX TA and is listed in the DEX™ Change Healthcare Registry website as "covered."
GeneTrails® Heme Fusion Gene Panel *(81456, 81479)* OHSU Knight Diagnostics Laboratories (OR)	MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38123) This test is listed in the DEX™ Change Healthcare Registry as "not covered" and is therefore considered **not medically necessary**.
GeneTrails® Comprehensive Solid Tumor Panel *(81445, 81479) and* ***GeneTrails® Solid Tumor Fusion Gene Panel*** *(81445, 81479)* OHSU Knight Diagnostics Laboratories (OR)	MolDX: Next-Generation Sequencing for Solid Tumors (L38119) and companion article A57901 These tests have completed a MolDX TA and is listed in the DEX™ Change Healthcare Registry website as "covered."
Genomic Prostate Score® (GPS) Test *(aka, Oncotype DX® Genomic Prostate Score) (0047U)* MDxHealth (CA)	MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease (L38339) and companion article A57372
Guardant360® *(0326U)* Guardant Health (CA) ***Note:*** *For the* ***Guardant360® CDx*** *test, see "Next Generation Sequencing Panel Tests Subject to the Medicare NCD 90.2" below.*	MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L39230) *Companion article A58973.* This test has completed a MolDX TA and is listed in the DEX™ Change Healthcare Registry website as "covered."
Guardant360 Response™ *(0422U, 81479) and*	MolDX: Minimal Residual Disease Testing for Cancer (L38814) and companion article A58454 The article includes specific guidance for these tests.

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE For Medicare Coverage Determinations and Articles, see the *Medicare Coverage Database* Back to Criteria
Guardant Reveal™ *(0569U)* Guardant Health (CA)	
HER2 (ERBB2) Testing *(0009U, 0338U, 81479)*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Molecular Diagnostic Tests (MDT) (L35160) and *companion article A57526* *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, CA, NV:* • MolDX: Molecular Diagnostic Tests (MDT) (L35160) and companion article A57526
InvisionFirst™ - Lung *(aka InVision) (0388U, 81479)* Inivata (NC)	MolDX: Inivata, InVisionFirst, Liquid Biopsy for Patients with Lung Cancer (L37870) and companion article A56924
IsoPSA® *(0359U) Cleveland Diagnostics (OH)*	Prostate Cancer Detection with IsoPSA® (L39284) and companion article A59066
KRAS Gene Tests *(81275)*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Molecular Diagnostic Tests (MDT) (L35160) and companion article A54498 The article states that "MolDX will allow future FDA approved and amended indications for these tests." To view FDA-approved KRAS tests and their corresponding medications, see the FDA List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools).
LiquidHALLMARK® *(0530U, 0571U)* Lucence Health (CA)	MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L39230) and companion article A58973
Lymph2Cx *(0017M) and* ***Lymph3Cx Lymphoma Molecular Subtyping Assay*** *(0120U)* Mayo Clinic Laboratory (AZ, MN, FL)	*Laboratory in AZ:* • The MolDX Program requires labs to submit a technology assessment (TA) to provide evidence of analytical and clinical validity (AV/CV), and clinical utility (CU). *(Noridian article A54554)* These tests are listed in the DEX™ Change Healthcare Registry as "not covered." Therefore, they are considered **not medically necessary**. *Laboratory in MN:*

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE For Medicare Coverage Determinations and Articles, see the *Medicare Coverage Database* Back to Criteria
	• Molecular Pathology Procedures (L35000) Gene expression profiling for certain cancers is listed in this LCD as a type of test that may not be covered. *Laboratory in FL:* • The LCD for *Molecular Pathology Procedures* (L34519) Gene expression profiling for certain cancers is listed in this LCD as a type of test that may not be covered.
MammaPrint® *(81521)* Agendia (CA)	MolDX: Molecular Diagnostic Tests (MDT) (L35160) and companion article A54445
Merlin™ Test *(0578U)* SkylineDx (CA)	MolDX: Melanoma Risk Stratification Molecular Testing (L37750) and companion article A57268 The test has completed a TA and is listed in the DEX™ Change Healthcare Registry website as "covered."
MGMT Gene Promoter Tests *(81287)*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: MGMT Promoter Methylation Analysis (L36188) and companion article A57432
MI Tumor Seek Hybrid *(81479)* Caris Life Science (AZ)	MolDX: Next-Generation Sequencing for Solid Tumors (L38119) and companion articles A57901 and A55624 The test has completed a TA and is listed in the DEX™ Change Healthcare Registry website as "covered."
Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Testing *(81301, 81479, 88341, 88342)*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Molecular Diagnostic Tests (MDT) (L35160) and companion artilcle A56103
Minimal Residual Disease (MRD) Testing	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, UT, WY, CA, NV:* • MolDX: Minimal Residual Disease Testing for Cancer (L38814) and companion articles A58454 (for solid tumors) and A58996 (for hematologic cancers) 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."
Molecular Biomarkers to Risk-Stratify Patients at	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:*

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE **For Medicare Coverage Determinations and Articles, see the** *Medicare Coverage Database* Back to Criteria
Increased Risk for Prostate Cancer	• MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39005) and companion article A58718
myPath Melanoma Assay *(81479, 0090U)* Myriad Genetics (UT)	MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma (L39373) and companion article A59179 This test has completed a TA and is listed in the DEX™ Change Healthcare Registry as "covered".
NGS Panel Tests for Cancer: FDA-Approved/Cleared • ***Agilent Resolution ctDx FIRST*** *(0397U) Agilent* • ***BRACAnalysis CDx*** *(81162) Myriad Genetics* • ***CRCdx® RAS Mutation Detection Kit*** *(0471U) EntroGen* • ***FoundationOne CDx™ (F1CDx)*** *(0037U) Foundation Medicine* • ***FoundationOne® Liquid CDx*** *(0239U) Foundation Medicine* • ***Guardant360® CDx*** *(0242U) Guardant Health* • ***MI Cancer Seek™*** *(0211U) Caris Life Sciences* • ***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 and OncoReveal™ CDx*** *(0523U) Pillar Biosciences* • ***Praxis™ Extended RAS Panel*** *(0111U) Illumina, Inc.*	For next generation sequencing (NGS) tests **with FDA-approval** or clearance as an approved companion diagnostic or in vitro test: • 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 testing* ***does not meet the NCD coverage criteria,*** *and local guidance should be applied (see NGS Panel Tests for Solid Tumors or Plasma-Based Panel Tests for Solid Tumors below).* **Additional Information:** ➢ 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 for the cancer type. ➢ The "Germline (Inherited) Cancer" testing section in this NCD refers only to **germline testing for inherited cancer risk**. It does **not** refer to somatic testing for targeted treatments in patients who are known to have an inherited cancer risk variant. Requests for somatic (e.g., tumor tissue) testing should only be reviewed with the "Somatic (Acquired) Cancer" criteria.

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE For Medicare Coverage Determinations and Articles, see the *Medicare Coverage Database* Back to Criteria
• ***TruSight™ Oncology Comprehensive*** *(0543U) Illumina, Inc.* • ***xT CDx*** *(0473U) Tempus*	
NGS Panel Tests for Myeloid Malignancies *(not FDA-approved or cleared as companion diagnostic tests for the cancer indication)* *Includes myeloproliferative neoplasms (MPN), myelodysplastic syndromes (MDS), overlapping MDS/MPN, and acute myeloid leukemia (AML)* *For non-NGS tests, see row for BCR-ABL Negative Myeloproliferative Disease Testing (non-NGS)*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38123) and companion article A57891 *Laboratories in NC, SC, AL, GA, VA, WV:* • MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38047) and companion article A57837
NGS Panel Tests for Solid Tumors *(not FDA-approved or cleared as companion diagnostic tests for the cancer indication)* *For plasma-based [liquid biopsy] genomic profiling panel tests, see applicable row below.*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Next-Generation Sequencing for Solid Tumors (L38119) and companion article A57901 *Laboratories in NC, SC, AL, GA, VA, WV:* • MolDX: Next-Generation Sequencing for Solid Tumors (L38045) and companion article A57831 The following tests have completed a TA and are listed in the DEX™ Change Healthcare Registry as "covered": ✓ Guardant360 TissueNext (0334U), Guardant Health ✓ Oncomine Dx Express Test (0648U), Thermo Fisher Scientific ✓ 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) and companion article A52986
Nodify CDT *(0360U)* Biodesix (CO and KS)	*Laboratory in KS:* • MolDX: Molecular Biomarkers for Risk Stratification of Indeterminate Pulmonary Nodules Following Bronchoscopy (L39711) and companion article A58511

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE **For Medicare Coverage Determinations and Articles, see the** *Medicare Coverage Database* Back to Criteria
	This test has completed a TA and is listed in the DEX™ Change Healthcare Registry as "covered." *Laboratory in CO:* • LCD Biomarkers for Oncology (L35396) and companion article A52986 do not specifically address this test or CPT code. In the absence of specific local guidance for Colorado, the guidance above for Kansas should be used.
NRAS Gene Tests *(81311, 81479)*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: NRAS Genetic Testing (L36335) and companion article A57486
NTRK Gene Fusion Tests (NTRK1, NTRK2, and NTRK3) *(81191, 81192, 81193, 81194)*	*Laboratories in all states:* According to the MolDX LCD L38043, "Larotrectinib, a TRK inhibitor, has received FDA approval for *NTRK* positive (without a known resistance mutation) tumors in patients with metastatic disease or where surgical resection is likely to result in severe morbidity, and who have no satisfactory alternative treatments or that have progressed following treatment." Targeted *NTRK* gene fusion testing may be considered **medically necessary** for individuals with a solid tumor for which an NTRK-inhibitor (e.g., VITRAKVI®/larotrectinib, 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)	According to the Medicare National Coverage Determinations Manual, unless specifically covered by NCD, 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 necessary**.
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, clinical documentation must detail how the test results will directly impact treatment, outcome and/or clinical management in the care of the beneficiary for individual review of the test.
Oncotype DX® AR-V7 Nuclear Detect *(81479)* Epic Sciences/Genomic Health (CA)	MolDX: Phenotypic Biomarker Detection from Circulating Tumor Cells (L38643) and companion article A58183 This LCD/article also addresses Biocept Target Selector HER2 Assay

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE For Medicare Coverage Determinations and Articles, see the *Medicare Coverage Database* Back to Criteria
Oncotype DX® Breast Recurrence Score *(aka Oncotype DX® Breast Cancer Assay) (81519)* Exact Sciences (CA and WI)	*Laboratory in CA:* • MolDX: Molecular Diagnostic Tests (MDT) (L35160) and companion article A54480 *Laboratory in WI:* • Molecular Pathology Procedures (L35000) and companion *article A56199* See LCD entry for "Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR of 21 genes."
Oncotype DX® Breast DCIS *(0045U)* Exact Sciences (CA)	MolDX: Oncotype DX® Breast Cancer for DCIS (Genomic Health™) (L36941) and companion article A57619
Oncotype DX® Colon Cancer Recurrence Score *(aka, Oncotype DX® Colon Cancer Assay) (81525)* Exact Sciences (CA and WI)	*Laboratory in CA:* • MolDX: Molecular Diagnostic Tests (MDT) (L35160) and companion article A54484 *Laboratory in WI:* • Molecular Pathology Procedures L35000 and companion article A56199
PanGIA Prostate *(0228U)* Genetics Institute of America by Entopsis *(FL)*	Molecular Pathology Procedures (L34519)
PathFinderTG® Tests, *Interpace Diagnostics (81479):* • ***BarreGEN®*** • ***PancraGEN®*** • ***PanDNA®***	*For PancraGen®:* • Genetic Testing in Oncology: Specific Tests (L39365) *For others:* • Loss-of-Heterozygosity Based Topographic Genotyping with PathfinderTG® (L34864) and companion article A56897
Percepta© Bronchial Genomic Classifier *(81479)* Veracyte, Inc. (CA)	MolDX: Molecular Biomarkers for Risk Stratification of Indeterminate Pulmonary Nodules Following Bronchoscopy (L39678) and companion article A59505
Dermtech™ Melanoma Test *(previously called the Pigmented Lesion Assay) (0089U)* DermTech (CA)	MolDX: Pigmented Lesion Assay (L38151) and companion article A58042
PIK3CA Gene Tests *(81309, 81404, 0155U, 0177U)*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:*

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE **For Medicare Coverage Determinations and Articles, see the** *Medicare Coverage Database* Back to Criteria
	• MolDX: Molecular Diagnostic Tests (MDT) (L35160) and companion article A57526 *For testing related to breast cancer treatment, see also:* • Billing and Coding: MolDX: PIK3CA Gene Tests (A55597) Certain tests, such as the therascreen® PIK3CA RGQ PCR are FDA-approved companion diagnostic tests and may be considered medically necessary 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 AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L39230) and companion article A58973 *Laboratories in IA, KS, MO, NE, IN, and MI:* • MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L38168) and companion article A57936 *Laboratories in NC, SC, AL, GA, VA, TN, and WV:* • MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L38043) and companion article A57867 *Laboratories in OH and KY:* • MolDX: Plasma-Based Genomic Profiling in Solid Tumors (L38065) and companion article A57917 According to these LCDs, “Other liquid biopsies will be covered for the same indications if they display similar performance in their intended used applications to Guardant360®.” Tests that do not have FDA-approval or clearance must be listed on the DEX™ Change Healthcare Registry website as a potentially covered test by MolDX for Medicare.
Prolaris™ Prostate Cancer Prognostic Test or Genomic Assay *(81541)* Myriad Genetics (UT)	MolDX: Prostate Cancer Genomic Classifier Assay for Men with Localized Disease (L38339) and companion article A57372 The LCD focuses on the Decipher® Prostate Cancer Classifier Assay but 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 has completed a TA and is listed in the DEX™ Change Healthcare Registry as “covered.”

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE **For Medicare Coverage Determinations and Articles, see the** *Medicare Coverage Database* Back to Criteria
ProMark Risk Score *(81479)* Metamark Genetics	MolDX: ProMark Risk Score (L36704) and companion article A57515
Prosigna Breast Cancer Assay *(81520)* LabCorp (any state) or Veracyte (CA)	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • MolDX: Breast Cancer Assay: Prosigna (L36380) and companion article A57363 *Laboratories in NC, SC, VA, WV, AL, TN, or GA:* • MolDX: Breast Cancer Assay: Prosigna (L36125) and companion article A56949
RiskReveal™ *(previously DetermaRx (0288U)* Razor Genomics (CA, TN)	*Laboratory in CA:* • MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer (L38327) and companion article A57329 *Laboratory in TN:* • MolDX: Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer (L38238) and companion article A58031
SelectMDx *(0339U)* MDxHealth (CA, TX)	*Laboratory in CA:* • MolDX: Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer (L39005) and companion article A58718 This test has completed a TA from the MolDX Program and is listed in the DEX™ Change Healthcare Registry website as “covered”. *Laboratory in TX:* • Biomarkers for Oncology (L35396) and companion article A52986 This test has completed a TA from the MolDX Program and is listed in the DEX™ Change Healthcare Registry website as “covered,” therefore, there is evidence that the test has proven clinical validity/utility as listed in the LCD.
SEPT9 Gene Tests *(81327)*	*Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY, CA, NV:* • Billing and Coding: MolDX: SEPT9 Gene Test (A55623)
Signatera™ *(0340U)* Natera (CA, TX)	*Laboratory in CA:* • MolDX: Minimal Residual Disease Testing for Solid Tumor Cancers (L38814) and companion article A58454 This test has completed a TA and is listed in the DEX™ Change Healthcare Registry as “covered.” *Laboratory in TX:*

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE **For Medicare Coverage Determinations and Articles, see the** *Medicare Coverage Database* Back to Criteria
	• LCD Biomarkers for Oncology (L35396) and companion article A52986 According to the DEX™ Change Healthcare Registry website, this test is listed as a covered test by MolDX for Medicare, indicating that it has demonstrated clinical validity/utility, as listed in the LCD.
ThyGenX (81445), **ThyGeNEXT** (0245U), and **ThyraMIR** (0018U, 81479) Interpace Diagnostics (NJ)	Biomarkers for Oncology (L35396) and companion article A52986 See the guideline specific to each test found within the LCD.
Thyroseq Genomic Classifier (0026U) Sonic Healthcare (NY)	Thyroid Nodule Molecular Testing (L38968) and companion article A58656
TissueCypher® Barrett's Esophagus Assay *(0108U)* Cernostics/Castle Biosciences (PA)	Biomarkers for Oncology (L35396)
Additional Tests That Are Not Covered	
ColonAiQ *(0453U)* Breakthrough Genomics (CA) ***ColoScape™*** *(0368U)* DiaCarta Clinical Lab (CA) ***Dawn IO Melanoma*** *(0357U)* Intervenn (CA) ***DCISionRT®*** *(0295U)* PreludeDx™ (CA) ***EarlyTect® Bladder Cancer Detection*** *(EarlyTect® BCD) (0452U)* Promis Diagnostics (CA) ***EpiSwitch® Checkpoint-inhibitor Response Test (CiRT)*** *(0332U)* Next Bio Research Services (VA) ***HelioHCC™ Strat*** *(0611U) and* ***HelioHCC™ Trace*** *(0612U)* Helio Genomics (CA)	The MolDX Program requires tests to complete a TA to provide evidence of analytical and clinical validity, and clinical utility. Reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review. The results of these TAs are published on the DEX™ Change Healthcare Registry website, with a "covered" or "not covered" determination. According to the DEX™ Registry, these tests are listed as "not covered" or they do not have a coverage determination and are therefore considered **not medically necessary**.

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE For Medicare Coverage Determinations and Articles, see the *Medicare Coverage Database*	Back to Criteria
Immunoscore *(0261U)* HalioDx or Veracyte (VA) ***Insight TNBCtype™*** *(0153U)* Insight Molecular Labs/Oncocyte Corporation (TN, CA) ***LungLB®*** *(0317U)* LungLife AI® (CA) ***MPS*** *(Mi-Prostate Score, previously MiPS) (0113U)* MLabs **(MI)** **mRNA CancerDetect™** (0296U) Viome Life Sciences (WA) ***MyAML*** *(0050U)* Laboratory for Personalized Molecular Medicine (CA) ***myChoice® HRD*** Myriad Genetics (UT) ***Northstar Response™*** *(0486U)* ***Oncuria® Detect*** *(0365U),* ***Oncuria® Monitor*** *(0366U),* ***Oncuria® Predict*** *(0367U)* DiaCarta Clinical Lab (CA) ***Pervenio™ Lung NGS*** *(25 genes) (81479)* Life Technologies™ (CA) ***Plasma Focus*** *(0562U)*, ***Plasma Complete (0585U), Plasma Detect Genome (0646U, 0647U)*** Labcorp ***PROSTOX™-Ultra*** *(0534U)* MiraDX (CA) ***Resolution ctDx Lung*** *(0179U)* Agilent/Resolution Biosciences (WA) ***Reveal Lung Nodule Characterization*** *(0092U)* MagArray, Inc. (CA)		

TEST INFORMATION	MEDICARE RATIONALE / REFERENCE **For Medicare Coverage Determinations and Articles, see the** *Medicare Coverage Database* Back to Criteria
HelioLiver *(0333U)* Fulgent Therapeutics (CA and TX)	***California*****:** LCD L35160 states that reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review. According to the DEX™ Change Healthcare Registry website, this test is "not covered". ***Texas*****:** This test is not listed in the LCD for *Biomarkers for Oncology* (L35396) or companion article (A52986) as a covered test. Under this LCD, additional considerations also include FDA labeling and NCCN recommendations. This test does not have FDA approval or clearance, and NCCN guidelines for Hepatocellular Carcinoma (v.2.2023) do not recommend it. Therefore, this test is considered **not medically necessary.**
Auria® *(0458U)* Namida Lab (AR) ***Galleri®*** *(81479)* Grail, Inc. (CA) ***TruD MDS Hepatocellular Carcinoma*** *(0620U)* **TruDiagnostic**™, (KY)	According to *Title XVIII of the Social Security Act, Section 1862(a)(1)(A)*: " ...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury..." Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law are statutorily excluded from Medicare coverage and are therefore considered **not medically necessary**.
CxBladder Triage, Triage Plus *(previously Detect+),* ***Detect,*** *and* ***Monitor*** *(0363U, 0420U, 0012M, 0013M)* Pacific Edge Diagnostics (PA)	Genetic Testing in Oncology: Specific Tests (L39365)
BBDRisk Dx™ *(0067U)* Silbiotech **(MD)** ***LC-MS/MS Targeted Proteomic Assay,*** *(0174U)* OncoOmicDx/mProbe	• 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 necessary**.

POLICY GUIDELINES

Important Notes Regarding Diagnostic Laboratory and Genetic Testing Services

Medicare and Medical Necessity

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

- Fall within a defined Medicare benefit category[1,2]

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

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

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

Services Excluded from Coverage

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

Molecular Diagnostic Services Program (MolDX)

The Medicare Molecular Diagnostic Services Program (MolDX) was developed in 2011 to identify and establish coverage and reimbursement for molecular diagnostic tests and is maintained by Palmetto GBA. Palmetto evaluates genetic tests to determine analytical and clinical validity and clinical utility, as well as confirming that each test meets Medicare criteria (described below). Palmetto MolDX guidelines provide assessments and indicate coverage or non-coverage of the test.[12-15]

For Testing Performed Outside of the Medicare Advantage Organization's Service Area

"A MAC outside of the plan's service area sometimes has exclusive jurisdiction over a Medicare covered item or service. In some instances, one Medicare A/B MAC processes all of the claims for a particular Medicare-covered item or service for all Medicare beneficiaries around the country. This generally occurs when there is only one supplier of a particular item, medical device or diagnostic test (for example; certain pathology and lab tests furnished by

independent laboratories). In this situation, MA plans must follow the coverage requirements or LCD of the MAC that enrolled the supplier and processes all of the Medicare claims for that item, test or service."[15]

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

REQUIRED DOCUMENTATION

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

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

CROSS REFERENCES

1. Genetic and Molecular Diagnostics – Testing for Inherited Cancer Risk, Genetic Testing, Policy No. M-GT02
2. Genetic and Molecular Diagnostics – Next Generation Sequencing, Genetic Panels, and Biomarker Testing, Genetic Testing, Policy No. M-GT64
3. Chemoresistance and Chemosensitivity Assays (CSRAs), Laboratory, Policy No. M-LAB06
4. Multimarker and Proteomics-based Serum Testing Related to Ovarian Cancer, Laboratory, Policy No. M-LAB60
5. Laboratory and Genetic Testing for Use of Fluoropyrimidine Chemotherapy (5-FU and Capecitabine) in Patients with Cancer, Laboratory, Policy No. M-LAB64

REFERENCES

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

CODING

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

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

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

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

Codes	Number	Description
		(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

Codes	Number	Description
		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	Genomic Prostate Score® (GPS) Test, MDxHealth, Inc, MDxHealth, Inc
	0048U	Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s)
	0049U	NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, quantitative
	0050U	Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements
	0067U	Oncology (breast), immunohistochemistry, protein expression profiling of 4 biomarkers (matrix metalloproteinase-1 [MMP-1], carcinoembryonic antigen-related cell adhesion molecule 6 [CEACAM6], hyaluronoglucosaminidase [HYAL1], highly expressed in cancer protein [HEC1]), formalin-fixed paraffin-embedded precancerous breast tissue, algorithm reported as carcinoma risk score
	0069U	Oncology (colorectal), microRNA, RT-PCR expression profiling of miR-31-3p, formalin-fixed paraffin-embedded tissue, algorithm reported as an expression score
	0080U	Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy
	0089U	Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es)
	0090U	Oncology (cutaneous melanoma) mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed

Codes	Number	Description
		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-

Codes	Number	Description
		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
	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

Codes	Number	Description
	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

Codes	Number	Description
		normal DNA specimens, fresh or formalinfixed paraffin-embedded (FFPE) tissue, blood or bone marrow, comparative sequence analyses and variant identification
	0298U	Oncology (pan tumor), whole transcriptome sequencing of paired malignant and normal RNA specimens, fresh or formalin-fixed paraffin-embedded (FFPE) tissue, blood or bone marrow, comparative sequence analyses and expression level and chimeric transcript identification
	0299U	Oncology (pan tumor), whole genome optical genome mapping of paired malignant and normal DNA specimens, fresh frozen tissue, blood, or bone marrow, comparative structural variant identification
	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

Codes	Number	Description
		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 high-risk patients, analysis of methylation patterns on circulating cell free DNA (cfDNA) plus measurement of serum of AFP/AFP-L3 and oncoprotein des-gamma-carboxy-prothrombin (DCP), algorithm reported as normal or abnormal result
	0334U	Oncology (solid organ), targeted genomic sequence analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, DNA analysis, 84 or more genes, 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

Codes	Number	Description
	0363U	Oncology (urothelial), mRNA, gene-expression profiling by real-time quantitative PCR of 5 genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm incorporates age, sex, smoking history, and macrohematuria frequency, reported as a risk score for having urothelial carcinoma
	0364U	Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (PCR) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (MRD) with quantitation of disease burden, when appropriate
	0365U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm, including patient's age, race and gender, reported as a probability of harboring urothelial bladder cancer
	0366U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of recurrent bladder cancer
	0367U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm reported as a risk score for probability of rapid recurrence of recurrent or persistent cancer following transurethral resection
	0368U	Oncology (colorectal cancer), evaluation for mutations of APC, BRAF, CTNNB1, KRAS, NRAS, PIK3CA, SMAD4, and TP53, and methylation markers (MYO1G, KCNQ5, C9ORF50, FLI1, CLIP4, ZNF132 and TWIST1), multiplex quantitative polymerase chain reaction (qPCR), circulating cell-free DNA (cfDNA), plasma, report of risk score for advanced adenoma or colorectal cancer
	0375U	Oncology (ovarian), biochemical assays of 7 proteins (follicle stimulating hormone, human epididymis protein 4, apolipoprotein A-1, transferrin, beta-2 macroglobulin, prealbumin [ie, transthyretin], and cancer antigen 125), algorithm reported as ovarian cancer risk score
	0376U	Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancerspecific mortality, includes predictive algorithm to androgen deprivationtherapy response, if appropriate
	0379U	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA (523 genes) and RNA (55 genes) by nextgeneration sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden
	0387U	Oncology (melanoma), autophagy and beclin 1 regulator 1 (AMBRA1) and loricrin (AMLo) by immunohistochemistry, formalinfixed paraffin-embedded (FFPE) tissue, report for risk of progression
	0388U	Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions

Codes	Number	Description
		and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection
	0391U	Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splicesite variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score
	0395U	Oncology (lung), multi-omics (microbial DNA by shotgun next generation sequencing and carcinoembryonic antigen and osteopontin by immunoassay), plasma, algorithm reported as malignancy risk for lung nodules in early-stage disease
	0398U	Gastroenterology (Barrett esophagus), P16, RUNX3, HPP1, and FBN1 DNA methylation analysis using PCR, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score for progression to high-grade dysplasia or cancer
	0403U	Oncology (prostate), mRNA, gene expression profiling of 18 genes, first-catch urine, algorithm reported as percentage of likelihood of detecting clinically significant prostate cancer
	0404U	Oncology (breast), semiquantitative measurement of thymidine kinase activity by immunoassay, serum, results reported as risk of disease progression
	0405U	Oncology (pancreatic), 59 methylation haplotype block markers, next-generation sequencing, plasma, reported as cancer signal detected or not detected
	0406U	Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer
	0409U	Oncology (solid tumor), DNA (80 genes) and RNA (36 genes), by next-generation sequencing from plasma, including single nucleotide variants, insertions/deletions, copy number alterations, microsatellite instability, and fusions, report showing identified mutations with clinical actionability
	0410U	Oncology (pancreatic), DNA, whole genome sequencing with 5-hydroxymethylcytosine enrichment, whole blood or plasma, algorithm reported as cancer detected or not detected
	0413U	Oncology (hematolymphoid neoplasm), optical genome mapping for copy number alterations, aneuploidy, and balanced/complex structural rearrangements, DNA from blood or bone marrow, report of clinically significant alterations
	0414U	Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (ALK, BRAF, EGFR, ERBB2, MET, NTRK1-3, RET, ROS1), and KRAS G12C and PD-L1, if performed, formalin-fixed paraffin embedded (FFPE) tissue, reported as positive or negative for each biomarker
	0418U	Oncology (breast), augmentative algorithmic analysis of digitized whole slide

Codes	Number	Description
		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
	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)
	0452U	Oncology (bladder), methylated PENK DNA detection by linear target enrichment-quantitative methylation-specific real-time PCR (LTE-qMSP), urine, reported as likelihood of bladder cancer
	0453U	Oncology (colorectal cancer), cellfree DNA (cfDNA), methylation based quantitative PCR assay (SEPTIN9, IKZF1, BCAT1, Septin9-2, VAV3, BCAN), plasma, reported as presence or absence of circulating tumor DNA (ctDNA)
	0458U	Oncology (breast cancer), S100A8 and S100A9, by enzymelinked immunosorbent assay (ELISA), tear fluid with age, algorithm reported as a risk score
	0464U	Oncology (colorectal) screening, quantitative real-time target and signal amplification, methylated DNA markers, including LASS4, LRRC4 and PPP2R5C, a reference marker ZDHHC1, and a protein marker (fecal hemoglobin), utilizing stool, algorithm reported as a positive or negative result

Codes	Number	Description
	0465U	Oncology (urothelial carcinoma), DNA, quantitative methylation specific PCR of 2 genes (ONECUT2, VIM), algorithmic analysis reported as positive or negative
	0467U	Oncology (bladder), DNA, next generation sequencing (NGS) of 60 genes and whole genome aneuploidy, urine, algorithms reported as minimal residual disease (MRD) status positive or negative and quantitative disease burden
	0470U	Oncology (oropharyngeal), detection of minimal residual disease by next-generation sequencing (NGS) based quantitative evaluation of 8 DNA targets, cell-free HPV 16 and 18 DNA from plasma
	0471U	Oncology (colorectal cancer), qualitative real-time PCR of 35 variants of KRAS and NRAS genes (exons 2, 3, 4), formalin fixed paraffin-embedded (FFPE), predictive, identification of detected mutations
	0473U	Oncology (solid tumor), next generation sequencing (NGS) of DNA from formalin-fixed paraffin embedded (FFPE) tissue with comparative sequence analysis from a matched normal specimen (blood or saliva), 648 genes, interrogation for sequence variants, insertion and deletion alterations, copy number variants, rearrangements, microsatellite instability, and tumor-mutation burden
	0478U	Oncology (non-small cell lung cancer), DNA and RNA, digital PCR analysis of 9 genes (EGFR, KRAS, BRAF, ALK, ROS1, RET, NTRK 1/2/3, ERBB2, and MET) in formalin-fixed paraffin-embedded (FFPE) tissue, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, and reported as actionable detected variants for therapy selection
	0481U	IDH1 (isocitrate dehydrogenase 1 [NADP+]), IDH2 (isocitrate dehydrogenase 2 [NADP+]), and TERT (telomerase reverse transcriptase) promoter (eg, central nervous system [CNS] tumors), next-generation sequencing (single-nucleotide variants [SNV], deletions, and insertions)
	0485U	Oncology (solid tumor), cell-free DNA and RNA by next-generation sequencing, interpretative report for germline mutations, clonal hematopoiesis of indeterminate potential, and tumor-derived single-nucleotide variants, small insertions/deletions, copy number alterations, fusions, microsatellite instability, and tumor mutational burden
	0486U	Oncology (pan-solid tumor), nextgeneration sequencing analysis of tumor methylation markers present in cell-free circulating tumor DNA, algorithm reported as quantitative measurement of methylation as a correlate of tumor fraction
	0487U	Oncology (solid tumor), cell-free circulating DNA, targeted genomic sequence analysis panel of 84 genes, interrogation for sequence variants, aneuploidycorrected gene copy number amplifications and losses, gene rearrangements, and microsatellite instability
	0490U	Oncology (cutaneous or uveal melanoma), circulating tumor cell selection, morphological characterization and enumeration based on differential CD146, high molecular–weight melanoma associated antigen, CD34 and CD45

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

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

Codes	Number	Description
	~~0550U~~	~~Oncology (prostate), enzyme-linked immunosorbent assays (ELISA) for total prostate-specific antigen (PSA) and free PSA, serum, combined with age, previous negative prostate biopsy status, digital rectal examination findings, prostate volume, and image and data reporting of the prostate, algorithm reported as a risk score for the presence of high-grade prostate cancer~~ (Deleted 1/1/2026)
	0558U	Oncology (colorectal), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted colorectal cancer protein marker (BF7 antigen), using serum, result reported as indicative of response/no response to therapy or disease progression/regression
	0559U	Oncology (breast), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted breast cancer protein marker (BF9 antigen), serum, result reported as indicative of response/no response to therapy or disease progression/regression
	0560U	Oncology (minimal residual disease [MRD]), genomic sequence analysis, cell-free DNA, whole blood and tumor tissue, baseline assessment for design and construction of a personalized variant panel to evaluate current MRD and for comparison to subsequent MRD assessments
	0561U	Oncology (minimal residual disease [MRD]), genomic sequence analysis, cell-free DNA, whole blood, subsequent assessment with comparison to initial assessment to evaluate for MRD
	0562U	Oncology (solid tumor), targeted genomic sequence analysis, 33 genes, detection of single-nucleotide variants (SNVs), insertions and deletions, copy-number amplifications, and translocations in human genomic circulating cell-free DNA, plasma, reported as presence of actionable variants
	0565U	Oncology (hepatocellular carcinoma), next-generation sequencing methylation pattern assay to detect 6626 epigenetic alterations, cell-free DNA, plasma, algorithm reported as cancer signal detected or not detected
	0566U	Oncology (lung), qPCR-based analysis of 13 differentially methylated regions (CCDC181, HOXA7, LRRC8A, MARCHF11, MIR129-2, NCOR2, PANTR1, PRKCB, SLC9A3, TBR1_2, TRAP1, VWC2, ZNF781), pleural fluid, algorithm reported as a qualitative result
	0569U	Oncology (solid tumor), next-generation sequencing analysis of tumor methylation markers (>20000 differentially methylated regions) present in cell-free circulating tumor DNA (ctDNA), whole blood, algorithm reported as presence or absence of ctDNA with tumor fraction, if appropriate
	0571U	Oncology (solid tumor), DNA (80 genes) and RNA (10 genes), by next-generation sequencing, plasma, including single-nucleotide variants, insertions/deletions, copy-number alterations, microsatellite instability, and fusions, reported as clinically actionable variants
	0572U	Oncology (prostate), high-throughput telomere length quantification by FISH, whole blood, diagnostic algorithm reported as risk of prostate cancer
	0573U	Oncology (pancreas), 3 biomarkers (glucose, carcinoembryonic antigen, and

Codes	Number	Description
		gastricsin), pancreatic cyst lesion fluid, algorithm reported as categorical mucinous or non-mucinous
	0578U	Oncology (cutaneous melanoma), RNA, gene expression profiling by real-time qPCR of 10 genes (8 content and 2 housekeeping), utilizing formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reports a binary result, either low-risk or high-risk for sentinel lymph node metastasis and recurrence
	0585U	Targeted genomic sequence analysis panel, solid organ neoplasm, circulating cell-free DNA (cfDNA) analysis from plasma of 521 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, and microsatellite instability, report shows identified mutations, including variants with clinical actionability
	0586U	Oncology, mRNA, gene expression profiling of 216 genes (204 targeted and 12 housekeeping genes), RNA expression analysis, formalin fixed paraffin-embedded (FFPE) tissue, quantitative, reported as log2 ratio per gene
	0591U	Oncology (prostate cancer), biochemical analysis of 3 proteins (total PSA, free PSA, and HE4), plasma, serum, prognostic algorithm incorporating 3 proteins and digital rectal examination, results reported as a probability score for clinically significant prostate cancer
	0592U	Oncology (hematolymphoid neoplasms), DNA, targeted genomic sequence of 417 genes, interrogation for gene fusions, translocations, rearrangements, utilizing formalin-fixed paraffin embedded (FFPE) tumor tissue, results report clinically significant variant(s)
	0597U	Oncology (breast), RNA expression profiling of 329 genes by targeted next generation sequencing and 20 proteins by multiplex immunofluorescence, formalin-fixed paraffin embedded (FFPE) tissue, algorithmic analyses to determine tumor-recurrence risk score
	0599U	Oncology (pancreatic cancer), multiplex immunoassay of ICAM1, TIMP1, CTSD, THBS1, and CA 19-9, serum, diagnostic algorithm reported as positive or negative
	0611U	Oncology (liver), analysis of over 1,000 methylated regions, cell-free DNA from plasma, algorithm reported as a quantitative result
	0612U	Oncology (liver), analysis of over 1,000 methylated regions, cell-free DNA from plasma, algorithm reported as a quantitative result
	0620U	Oncology (hepatocellular carcinoma), DNA methylation analysis of more than 5,000 sites, whole blood, algorithm reported as positive or negative risk
	0630U	Oncology (breast), mRNA, gene expression profiling by micro-array of 80 genes (80 content and 465 housekeeping), utilizing formalin-fixed paraffin-embedded tissue (FFPE), algorithm reported as index that is diagnostic of a molecular subtype (luminal, basal, Her2)
	0631U	Oncology (solid tumor), DNA, sequence analysis of 15 genes including BRCA1 and BRCA2 for identification of clonal hematopoiesis, blood, reported derived or nontumor derived

Codes	Number	Description
	0641U	Oncology (minimal residual disease [MRD]), tumor DNA, next-generation sequencing (NGS), using formalin-fixed paraffin-embedded (FFPE) tissue and blood samples, initial (baseline) assessment
	0642U	Oncology (minimal residual disease [MRD]), tumor DNA, next-generation sequencing (NGS), whole blood, comparison to previously performed analyses, reported as trend in circulating tumor DNA (ctDNA) level
	0643U	Oncology (genitourinary cancer), cell-free circulating tumor DNA (ctDNA), 200 genes, next-generation sequencing (NGS), interrogation for single nucleotide variants (SNVs), insertions/deletions, gene rearrangements, copy number alterations, and tumor mutation burden, using urine, identify and report mutations with clinical actionability
	0644U	Oncology (leukemia), minimal residual disease (MRD) detection for rearrangements, blood or bone marrow, personalized assay design and baseline quantification
	0645U	Oncology (leukemia), minimal residual disease (MRD) detection for rearrangements, based on digital PCR, blood or bone marrow, reported as not detected or detected with estimated abundance
	0646U	Oncology (molecular residual disease), whole genome sequence analysis, cell-free DNA, whole blood, and formalin-fixed paraffin embedded (FFPE) tumor tissue DNA, baseline assessment
	0647U	Oncology (molecular residual disease), whole genome sequence analysis, cell-free DNA (cfDNA), whole blood, assessment utilizing patient specific tumor information, reported as negative or percent circulating tumor DNA (ctDNA)
	0648U	Oncology (solid tumor), targeted genomic sequencing analysis, to detect deletions, insertions, and substitutions in 42 genes, copy number amplifications in 10 genes, and fusions and splice variants in 18 driver genes from DNA and RNA extracted from formalin fixed paraffin-embedded (FFPE) tissue
	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, DMA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis (ie, detection of large gene rearrangements)
	81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
	81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)

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

Codes	Number	Description
	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

Codes	Number	Description
		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)

Codes	Number	Description
	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

Codes	Number	Description
		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

Codes	Number	Description
	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

Codes	Number	Description
		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.