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Medicare Advantage Policy Manual **Policy ID:** M-GT64

Genetic and Molecular Diagnostics – Next Generation Sequencing and Genetic Panel Testing

Published: 10/01/2019

Next Review: 07/2020

Last Review: 09/2019 ***Medicare Link(s) Revised:*** *10/01/2019*

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.

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 the Centers of Medicare and Medicaid Services (CMS) policies, when available. 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 CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and 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.

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 testing is done for several purposes, including, but not limited to, diagnosing or predicting susceptibility for inherited conditions, determining carrier status, diagnostic and prognostic testing, screening for common disorders, or selecting appropriate treatments (also known as pharmacogenetic testing).

Panel testing technology, such as next generation sequencing and chromosomal microarray, is a genetic testing method that examines multiple genes or mutations simultaneously.

Panels using next generation technology are currently available in the areas of cancer, cardiovascular disease, neurologic disease, psychiatric conditions, and for reproductive testing. Design and composition of genetic panel tests have not been standardized. Panel tests vary by laboratory, and different commercial products for the same condition may test different sets of genes. In addition, the composition of any individual panel is likely to change over time, as new mutations are discovered and added to the existing panels.

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

MEDICARE ADVANTAGE POLICY CRITERIA

I. See Table 3 to determine if a panel 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 in order for the genetic test to be considered medically appropriate.

    a. Note, the genes and codes included in this table are provided as a courtesy and may not be exact. Individual laboratories may choose to use different coding, and gene lists are subject to change.

II. If the test in question is not part of Table 3, 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:

        i. The MolDX Program has determined certain gene tests do not meet Medicare's medical necessary requirements, and that the inclusion of these genes will result in an entire panel to be denied. These excluded genes are listed in Table 2.

        ii. Unless indicated otherwise, genetic testing panels which include any of the gene components in Table 2 are denied as statutorily excluded and not medically necessary tests under the MolDX Program and §1862(a)(1)(A) of the Social Security Act because the clinical utility requirements for a Medicare Benefit have not been satisfied. These panels are included in Table 3, and would be considered "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member…"

iii. Additional research may be necessary for panel tests that are:
    1. Performed in a geographical area that has adopted MolDX guidelines, ***BUT***
    2. That are not included within Table 3, ***AND***
    3. When none of the gene tests listed in Table 2 are included.

b. For Medicare jurisdictions which have **NOT** adopted MolDX Program guidelines:

    i. Additional research may need to be performed to determine the applicable Medicare guideline for panel tests performed in a geographical area that has not yet adopted MolDX guidelines when not included within Table 3.

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: Excluded Genes Which Result In Denied Panel Tests					Back to Criteria
Note: *This list was accurate at the time of publication, but is subject to change by the MolDX contractor. Use the provided link for each gene to confirm up-to-date non-coverage determinations.*					
ACVRL1*	ATP7B	BCKDHB	BLM	CFTR	CHD7
CYP2B6	ENG*	FANCC	GBA	HAX1	HBB
HEXA	IKBKAP	MCOLN1	MECP2	MMACHE	SMPD1
SULT4A1	VEGFR2				

***Exceptions for ACVRL1/ENG Testing:** For small, targeted panel tests, in which all other components are approved gene tests, exceptions may be made for ACVRL1 and ENG for patients with 'suspected' hereditary hemorrhagic telangiectasia, or HHT. Additional research may be necessary for coverage determinations of panels which may be denied solely due to the inclusion of these two (2) genes.

Table 3: Panel Test, Performing Laboratory and Location With Medicare Coverage References					
Note: The tests listed in Table 3 have known Medicare guidance available. Some tests are considered "not medically necessary," while others may have coverage criteria which must be met in order for the genetic test to be considered medically appropriate. Please review the "Medicare Rationale/Reference" source carefully.					
TEST NAME & GENES *If known*	**CODES** *If known*	**PERFORMING LABORATORY & LOCATION**	**COVERAGE AVAILABLE?** *When criteria met* **Yes**	**No**	**MEDICARE RATIONALE / REFERENCE** Back to Criteria
4kscore®	81539	Bio Reference Laboratories Inc. (New Jersey)		**X**	4Kscore Test Algorithm (L37792) *(Applies to the indicated performing laboratory) (See also the LCA for Coding for 4Kscore Test Algorithm, A56281)* If performed in other locations/states, see these additional references: ✓ MolDX: 4Kscore Assay (L36763) *(Laboratories in NC, SC, AL, GA, TN, VA, WV)* ✓ MolDX: 4Kscore Assay (L37122) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* ✓ MolDX: 4Kscore Assay (L37120) *(Laboratories in CA and NV)* ✓ Biomarker Testing (Prior to Initial Biopsy) for Prostate Cancer Diagnosis (L37733) *(Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT)* ✓ 4Kscore Test Algorithm (L37792) *(Laboratories in CO, NM, OK, TX, AK, LA, MS, DE, MD, PA)* ✓ MolDX: 4Kscore Assay (L37013) *(Laboratories in IA, KS, MO, NE, IN, MI)*

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					✓ Noncovered Service - 4Kscore Test Algorithm (L37798) *(Laboratories in FL)* ✓ MolDX: 4Kscore Assay (L36979) *(Laboratories in KY and OH)*	
Accelerate PhenoTest™ BC kit	0086U	Accelerate Diagnostics, Inc. (Arizona)	**X**		MolDX® Program Manual (see Section 2.3, for "Excluded Tests"): • As with any diagnostic laboratory test, Medicare requires the test be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." • Therefore, if signs/symptoms exist with suspicion of an infectious disease that would directly warrant and prompt testing for detection and the initiation of treatment, then the test may be considered medically necessary. • If performed in the absence of signs or symptoms, then the test would be considered screening.	
Afirma™ Assay *(Veracyte®)*	81545	Veracyte®	**X**		MolDX: Afirma™ Assay by Veracyte Billing and Coding Guidelines (A54358) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* MolDX: Afirma™ Assay by Veracyte Billing and Coding Guidelines (A54356) *(Laboratories in CA and NV)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					Biomarkers for Oncology (L35396)[16-18] *(Laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA). (Use the guideline specific to Afirma™ found within the LCD. For testing frequency allowance and ICD-10 code guidance, see also the LCA A52986.)*	
AlloSure® Donor-Derived Cell-Free DNA Test	81479	CareDx, Inc., Brisbane, CA	**X**		AlloSure® Donor-Derived Cell-Free DNA Test (L37303) *(Applies to the indicated performing laboratory)*	
Apifiny®	0021U	Armune BioScience, Inc. (Ann Arbor, MI)		**X**	• 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). *(WPS LCA A55391)* • The Wisconsin Physician Services (WPS) LCD L36807 states reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • This test is not considered medically reasonable and necessary until a MolDX review is complete and coverage is indicated by MolDX or WPS.	
Arrhythmogenic Right Ventricular	81479	Any laboratory in the states of Washington,		**X**	MolDX: Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C) Testing Billing and Coding Guidelines (A54976)	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
Dysplasia/Cardiomyopathy (ARVD/C) Testing		Oregon, Idaho, Utah, or California			*(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* MolDX: Arrhythmogenic Right Ventricular Dysplasia/Cardiomyopathy (ARVD/C) Testing Billing and Coding Guidelines (A54975) *(Laboratories in CA and NV)*	
BBDRisk Dx™	0067U	Silbiotech, Inc. (Gaithersburg, MD)			Biomarkers for Oncology (L35396) *(Applies to the indicated performing laboratory)* *This LCD states, "…biomarkers must have proven clinical validity/utility (CVU)." The LCD also states, "Biomarkers not addressed in this LCD or any other Novitas LCD will be considered not reasonable and necessary unless specifically covered by national policy." The biomarkers included in this test are not listed as approved biomarker tests by this Medicare contractor, and are not noted as having proven clinical validity/utility. Therefore, this test is not considered medically reasonable or necessary at this time.*	
BCR-ABL Negative Myeloproliferative Disease testing *(BCR/ABL1, JAK2, CALR, MPL)* *(Only when a panel test - for single gene tests, see Cross References)*	81206, 81207, 81208, 81219, 81270, 81402, 81403, 81445, 81450, 81455, and/or 81479	Any laboratory in the states of Washington, Oregon, Idaho, Utah, or California	**X**		MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36186) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36180) *(Laboratories in CA and NV)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					For both LCDs: If a treating physician suspects a patient has myeloproliferative neoplasms (MPN) or myelodysplastic syndromes (MDS), it would be clinically appropriate to test BCR-ABL. No specific criteria are provided for this gene directly as this is considered "step one" in the LCDs and would be considered "medically necessary" for these and related indications, as outlined in the LCDs.	
BDX-XL2					See M-GT20 for the Xpresys Lung 2® and BDX-XL2 tests.	
BluePrint®	81479	Agendia (Irvine, CA)		**X**	MolDX: BluePrint® Billing and Coding (A55115) *(Applies to the indicated performing laboratory)*	
BRACAnalysis® Rearrangement Test (BART)	81213	Myriad Genetics (Utah)	**X**		MolDX: BRCA1 and BRCA2 Genetic Testing (L36163) *(Applies to the indicated performing laboratory)*	
BRACAnalysis CDx *(BRCA1 and BRCA2)*	81479	Myriad Genetics, Utah	**X**		MolDX: Myriad's BRACAnalysis CDx™ Billing and Coding Guidelines (A55295) *(Applies to the indicated performing laboratory)*	
BRCA1 and BRCA2 Genetic Testing Panels *(any multi-gene panel for hereditary ovarian and breast cancer [HBOC] syndromes when performed in the state listed to the right)*	Various	Florida	**X**		BRCA1 and BRCA2 Genetic Testing (L36499) *(Laboratories in FL) See all sections related to multi-gene panel testing within the LCD.*	
BRCA1/2 *(BRCA1 and BRCA2)*	81162, 0138U	Ambry Genetics (Aliso Viejo, CA)	**X**		MolDX: BRCA1 and BRCA2 Genetic Testing (L36161) *(Applies to the indicated performing laboratory)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met*		MEDICARE RATIONALE / REFERENCE	Back to Criteria
			Yes	No		
With or without the +RNAinsight™ for BRCA1/2 add-on test					If criteria for BRCA1/2 are met, the +RNAinsight™ for BRCA1/2 may also be allowed if performed.	
BRCA1/2 *(BRCA1 and BRCA2)*	81162	Myriad Genetics (Utah)	**X**		MolDX: BRCA1 and BRCA2 Genetic Testing (L36163) *(Applies to the indicated performing laboratory)*	
BRCA1 Analysis *(BRCA1)*	81214	Ambry Genetics (Aliso Viejo, CA)	**X**		MolDX: BRCA1 and BRCA2 Genetic Testing (L36161) *(Applies to the indicated performing laboratory)*	
BRCAplus™ *(BRCA1, BRCA2, CDH1, PALB2, PTEN, and TP53)*	81479, 0129U	Ambry Genetics (Aliso Viejo, CA)		**X**	MolDX: BRCA1 and BRCA2 Genetic Testing (L36161) *(Applies to the indicated performing laboratory)* *(The LCD requires all genes included in a panel test to be relevant to the individual being tested; however, some genes in this panel have been determined to be excluded genetic tests [e.g., CDH1 and TP53]. When genes are included in a panel that have been determined to be excluded from Medicare coverage, the panel as a whole cannot be considered medically reasonable or necessary under Palmetto GBA MolDX Program, and the Social Security Act, §1862(a)(1)(A). See also the LCA A54897 which reads, "The inclusion of genes without specific proven clinical utility for a particular disease is either screening or considered research/investigational, and as such, is not a Medicare benefit.")*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met*		MEDICARE RATIONALE / REFERENCE	Back to Criteria
			Yes	No		
BRCAplus-Expanded *(ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, and TP53)*	81479	Ambry Genetics (Aliso Viejo, CA)		X	MolDX: BRCA1 and BRCA2 Genetic Testing (L36161) *(Applies to the indicated performing laboratory)* *(The LCD requires all genes included in a panel test to be relevant to the individual being tested; however, some genes in this panel have been determined to be excluded genetic tests [e.g., CDH1 and TP53]. When genes are included in a panel that have been determined to be excluded from Medicare coverage, the panel as a whole cannot be considered medically reasonable or necessary under Palmetto GBA MolDX Program, and the Social Security Act, §1862(a)(1)(A). See also the LCA A54897 which reads, "The inclusion of genes without specific proven clinical utility for a particular disease is either screening or considered research/investigational, and as such, is not a Medicare benefit.")*	
Breast Cancer Index℠ (aka BCI)	81479, 81518	bioTheranostics, Inc. (San Diego, CA)	X		MolDX: Breast Cancer Index™ (BCI) Gene Expression Test (L37822) Prior to 4/16/2019, LCD L36314 would have applied. For newly diagnosed patient's, LCD L37794 would be used.	
Breast Cancer Treatment and Management Panel tests *(breast cancer panel testing when performed in the state listed to the right)*	Various	Florida	X		Gene Expression Profiling Panel for use in the Management of Breast Cancer Treatment (L33586) *(Laboratories in FL)* ***Important Note:*** *Many tests in this LCD will be under different Medicare contractor jurisdiction.*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	 No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
Examples: • Oncotype DX™ • Prosigna™ Breast Cancer Prognostic Gene Signature Assay • MammaPrint® • Breast Cancer Gene Expression Ratio • Rotterdam 76-Gene Signature • The 41-gene signature assay • Amsterdam 70-Gene Profile					*Confirm the location of the laboratory performing the test prior to using this LCD. If the test is not going to be performed in Florida, do not use this LCD.*	
BreastNext *(17 genes - ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, MRE11A, MUTYH, NBN, NF1, PALB2, PTEN, RAD50, RAD51C, RAD51D, and TP53)* ***With or without the +RNAinsight™ for BreastNext® add-on test***	81479, 0102U, 0131U	Ambry Genetics (Aliso Viejo, CA)		**X**	MolDX: BRCA1 and BRCA2 Genetic Testing (L36161) *(Applies to the indicated performing laboratory)* *(The LCD requires all genes included in a panel test to be relevant to the individual being tested; however, some genes in this panel have been determined to be excluded genetic tests [e.g., CHEK2]. When genes are included in a panel that have been determined to be excluded from Medicare coverage, the panel as a whole cannot be considered medically reasonable or necessary under Palmetto GBA MolDX Program, and the Social Security Act, §1862(a)(1)(A). See also the LCA A54897 which reads, "The inclusion of genes*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					without specific proven clinical utility for a particular disease is either screening or considered research/investigational, and as such, is not a Medicare benefit.") **Note:** As an add-on code for *the BreastNext* test, +RNAinsight™ for BreastNext® by Ambry Genetics (0137U) is also non-covered if performed.	
CancerNext *(34 genes – APC, ATM, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, DICER1, EPCAM, GREM1, HOXB13, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, POLD1, POLE, PTEN, RAD50, RAD51C, RAD51D, SMAD4, SMARCA4, STK11, TP53)* ***With or without the +RNAinsight™ for CancerNext® add-on test***	81479, , 0134U	Ambry Genetics (Aliso Viejo, CA)		**X**	MolDX: BRCA1 and BRCA2 Genetic Testing (L36161) *(Applies to the indicated performing laboratory)* *(The LCD requires all genes included in a panel test to be relevant to the individual being tested; however, some genes in this panel have been determined to be excluded genetic tests [e.g., CHEK2 and STK11]. When genes are included in a panel that have been determined to be excluded from Medicare coverage, the panel as a whole cannot be considered medically reasonable or necessary under Palmetto GBA MolDX Program, and the Social Security Act, §1862(a)(1)(A). See also the LCA A54897 which reads, "The inclusion of genes without specific proven clinical utility for a particular disease is either screening or considered research/investigational, and as such, is not a Medicare benefit.")* **Note:** As an add-on code for *the CancerNext* test, +RNAinsight™ for CancerNext® by Ambry Genetics (0134U) is also non-covered if performed.	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
CancerNext Expanded *(67 genes – too many to list in full, but panel includes BLM and FANCC))*	81479	Ambry Genetics (Aliso Viejo, CA)		**X**	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. MolDX has determined panels may be denied as "not medically necessary" when certain non-covered gene tests (see Table 2) are included because they do not meet Medicare's medical necessity requirements. This panel is "not medically necessary" because it includes at least one of these specific excluded gene tests from Table 2.	
CancerTypeID®	81479 or 81540	bioTheranostics, Inc. (San Diego, CA)	**X**		MolDX: bioTheranostics Cancer TYPE ID® Billing and Coding Guidelines (A54386) *(Applies to the indicated performing laboratory)*	
CardiaRisk™ *(AGT genes)*	81479	Myriad Genetics (Utah)		**X**	MolDX: Biomarkers in Cardiovascular Risk Assessment (L36362) *(Applies to the indicated performing laboratory) See the bulleted non-covered list, and the specific bullet for the CardiaRisk™ test found within the LCD.*	
Cardiovascular risk genetic panel tests *(any cardiovascular risk panel test, including those that test genes Factor II (F2), Factor V (F5), MTHFR, CBS, MTR, MTRR, and/or MMADHC, when performed in any of the states listed to the right)*	81240, 81241, 81291, 81401, 81403, 81405, 81406, and/or 81479	Any laboratory in the states of Washington, Oregon, Idaho, Utah, or California *(See the row for "Pharmacogenetic panel tests" in table below for*		**X**	For the ***gene MMADHC***: ✓ LCD attachment for L36256, Excluded Test List – as of 08/01/2016 *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* ✓ LCD attachment for L35160, Excluded Test List – as of 08/01/2016 *(Laboratories in CA and NV)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
		similar testing performed by Boston Heart Diagnostics)			For the ***remaining genes (F2, F5, MTHFR, CBS, MTR, MTRR):*** ✓ MolDX: Biomarkers in Cardiovascular Risk Assessment (L36362) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* ✓ MolDX: Biomarkers in Cardiovascular Risk Assessment (L36358) *(Laboratories in CA and NV)* *For both LCDs, see the bulleted non-covered list, the specific bullet for cardiovascular risk panels, and the "**Gene Mutations (any methodology) and Genomic Profiling**" section found within the LCD.*	
CGI Tissue of Origin® *(Formerly known as the ResponseDX: Tissue of Origin and Pathwork® Tissue of Origin tests)*	81504	Cancer Genetics Inc. (Los Angeles, CA)	**X**		MolDx: ResponseDX Tissue of Origin® Billing and Coding Guidelines (A54494) *(Applies to the indicated performing laboratory)*	
clonoSEQ®	81479	Adaptive Biotechnologies	**X**		MolDX: Clonoseq® Assay for Assessment of Minimal Residual Disease (MRD) in Patients with Specific Lymphoid Malignancies (A56323) *(While this LCA was not effective until 3/4/2019, the LCA states coverage for the test when criteria are met is retroactively effective 3/16/2018.)*	
COLARIS® *(MLH1, MSH2, EPCAM, MSH6, PMS2 and MYH)*	81479	Myriad Genetics (Utah)	**X**		MolDX: Genetic Testing for Lynch Syndrome (L36374) *(Applies to the indicated performing laboratory) See the "**Definitive Molecular Testing for Lynch Syndrome**" section found within the LCD where it addresses molecular testing for*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					genes by NGS. (Until 4/16/2019, see also the LCD L35024 for potential additional indications. As of 4/16/2019, the LCD L36374 will be updated to align with L35024.)	
COLARIS® AP *(APC and MYH [MUTYH] genes only)*	81201-81203, 81403, 81406, 81479	Myriad Genetics (Utah)	**x**		MolDX: APC and MUTYH Gene Testing (L36884) *(Applies to the indicated performing laboratory)*	
Cologuard™ Colorectal Screening	81528	Exact Sciences Laboratories	**X**		NCD for Colorectal Cancer Screening Tests (210.3)	
ColonSentry®	81479	Innovative Diagnostic Laboratory (Richmond, VA)		**X**	The ColonSentry® panel is 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..." The ColonSentry® test is a “pre-screening” screening test, performed in the absence of signs and symptoms, and recommended as a test prior to other screening tests that are Medicare-approved. Therefore, it is not medically necessary based on the Medicare Benefit and medical necessity requirements.	
ColoNext *(17 genes - APC, BMPR1A, CDH1, CHEK2, EPCAM, GREM1, MLH1, MSH2, MSH6, MUTYH, PMS2,*	81479, 0101U, 0130U	Ambry Genetics (Aliso Viejo, CA)	**X**		MolDX: Genetic Testing for Lynch Syndrome (L36370) *(Applies to the indicated performing laboratory) (Until 4/16/2019, see also the LCD L35024 for potential additional indications. As of 4/16/2019, the LCD L36370 was updated to align with L35024.) (*According to this LCD, a stepped testing approach is required, which includes MSI/IHC	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	 No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
POLD1, POLE, PTEN, SMAD4, STK11, TP53) ***With or without the +RNAinsight™ for ColoNext® add-on test***					testing as the first step, or a multigene panel *inclusive* of MSI testing. If a lab is unable to perform the stepped testing approach outlined in the LCD, multiple germ-line gene testing will be covered by Medicare only for the findings noted in Criterion III, under the "**MMR Germline Gene Mutation Testing Exception**" subheading. • If the patient did have IHC/MSI testing first, then the ColoNext panel would **not** meet medical necessity criteria because this lab would have been capable of performing a stepped approach to testing using the Lynch Syndrome panel component tests they offer. • The ColoNext panel may be considered medically necessary if there is no tumor sample available for testing, ***and*** the patient meets one of the last two (2) criteria under the above noted "Exceptions" section. This is supported by the statement within the LCD that reads, "Labs performing MMR germ-line panels without appropriate selection of targeted genes based on patient data, screening test (MSI/IHC) results, or exceptions are not reasonable and necessary.") • If criteria for ColoNext® are met, the +RNAinsight™ for ColoNext® by Ambry Genetics (0130U) may also be allowed if performed.	
COMPASS® Bone Marrow Evaluation *(Genes include, but may not be limited to, ASXL1, CBL, DNMT3A, ETV6, EZH2, IDH1, IDH2, JAK2, KIT, MPL, NPM1, NRAS, PHF6, RUNX1, SETBP1, SF3B1,*	81270, 81310, 81403, 81404, 81405, and/or 81479	Genoptix, Carlsbad, CA		**X**	Certain tests (i.e., JAK2 or MPL) may be medically necessary for an individual, but this panel includes both medically appropriate and inappropriate gene tests. The clinical utility of several gene components in this panel has not been demonstrated, and most of the gene components of this test have been reviewed by MolDX and determined to not meet Medicare's requirements	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
SRSF2, TET2, TP53, U2AF1 and ZRSR2)					for coverage *(ASXL1, CBL, DNMT3A, EZH2, PHF6, SETBP1, SF3B1, SRSF2, TET2, TP53, U2AF1, and ZRSR2).* 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).	
Comprehensive BRACAnalysis® *(BRCA1 and BRCA2)*	81211	Myriad Genetics (Utah)	**X**		MolDX: BRCA1 and BRCA2 Genetic Testing (L36163) *(Applies to the indicated performing laboratory)*	
Comprehensive Genomic Profile Testing for Non-Small Cell Lung Cancer (NSCLC) *For FoundationOne Testing, (see separate row below)*	81445, 81455, and/or 81479	Multiple Laboratories perform tests under various names.	**X**		Retired Genomic Sequence Analysis Panels in the Treatment of Non-Small Cell Lung Cancer (L36376) (For services **between 4/1/2016 and 4/1/2019**) *(Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT)* Genomic Sequence Analysis Panels in the Treatment of Solid Organ Neoplasms (L37810) (For services **on and after 4/1/2019**) *(Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT)* Molecular Pathology Procedures (L35000) *(Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, or VT)* NCD 90.2 does not address all NGS tests. According to NCD 90.2, coverage for any NGS test not addressed by the NCD is at local contractor discretion. The LCDs for NSCLC by the local contractors Noridian and Palmetto were retired last	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					September with the development of NCD 90.2. Therefore, until new LCDs for lung or solid tumors are developed, apply the following references for the noted service areas: ✓ Retired MolDX: NSCLC, Comprehensive Genomic Profile Testing (L36198) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* ✓ Retired MolDX: NSCLC, Comprehensive Genomic Profile Testing (L36194) *(Laboratories in CA and NV)* ✓ Retired Palmetto GBA LCD for MolDX: NSCLC, Comprehensive Genomic Profile Testing (L36143) *(Laboratories in NC, SC, AL, GA, VA, WV)*	
ConfirmMDx™	81551	MDxHealth (Irvine, CA)	**X**		MolDX: ConfirmMDx Epigenetic Molecular Assay (L36327) *(Applies to the indicated performing laboratory)*	
Corus® CAD	81493	CardioDX, Redwood City, CA		**X**	**Effective 02/10/2019**: ✓ MolDX: Corus® CAD Assay (L37673) *(Applies to the indicated performing laboratory)* For services **prior to 02/10/2019**: ✓ Retired MolDX: Corus® CAD Test Billing and Coding Guidelines (A54429) *(Applies to the indicated laboratory)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					Instructions: Highlight A54429, and press Control + C to copy. Click on the LCA A54429 link above. Click "Search" from the option bar near the top of the screen. Enter (or paste) the LCA number into the "ID Search" field. The date of service can be left blank. Click the "Search Now" button.button. Apply the diagnosis (ICD-10) code instruction within LCA A54429 to determine medical necessity for Corus® CAD testing. All other indications (diagnoses) will deny as not medically necessary.	
CxBladder	81479, 0012M, 0013M	Pacific Edge Diagnostics USA Ltd (Hershey, PA)		**X**	Biomarkers for Oncology (L35396) *(Applies to the indicated performing laboratory)* *The Revision History Information from 10/4/2018 reads, "Non-coverage reaffirmed for CPT codes 0012M and 0013M for CxBladder." Another entry dated 02/01/2017 reads, "After review of the submitted literature it has been determined that non-coverage of CxBladder will remain."* *Finally, this LCD states, "Biomarkers not addressed in this LCD or any other Novitas LCD will be considered not reasonable and necessary unless specifically covered by national policy"* *CxBladder is not listed as an approved test by this Medicare contractor, and therefore, is not medically necessary at this time.*	
Decipher® Prostate Cancer Classifier Assay	81479	GenomeDX (San Diego, CA)	**X**		For ***Intermediate or High Risk Disease***:	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	 No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
(Decipher Biopsy and Decipher Post-Op)					✓ MolDX: Decipher® Prostate Cancer Classifier Assay (L36343) *(Applies to the indicated performing laboratory)* For ***Very Low and Low Risk Disease*** (stage T1 or T2): ✓ MolDX: Decipher® Biopsy Prostate Cancer Classifier Assay for Men with Very Low and Low Risk Disease (L37785) ✓ MolDX: Decipher® Biopsy Prostate Cancer Classifier Assay for Men with Very Low and Low Risk Disease (L37818) *(Effective 5/27/2019)* *The Decipher Biopsy and the Decipher Post-Op are technically the same test, and both are marketed under the name* Decipher® Prostate Cancer Classifier Assay. *Therefore, the LCDs apply to both versions.*	
Decision DX-GBM (Glioblastoma multiforme)	84999	Castle Biosciences Inc. (Arizona)	**X**		Retired Decision DX-GMB Billing Instruction (A52955) *(Applies to the indicated performing laboratory) (If this test is performed to determine a patient's treatment plan for a glioblastoma brain tumor, then the service may be considered medically reasonable and necessary.)* **Instructions:** Highlight A52955, and press Control + C to copy. Click on the LCA A52955 link above.	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met*		MEDICARE RATIONALE / REFERENCE	Back to Criteria
			Yes	No		
					Click "Search" from the option bar near the top of the screen. Enter (or paste) the LCA number into the "ID Search" field. The date of service can be left blank. Click the "Search Now" button.	
Decision DX-LEA	84999	Castle Biosciences Inc. (Arizona)		**X**	Non-Covered Services (L35008) *(Applies to the indicated performing laboratory)*	
Decision DX-Melanoma	81599	Castle Biosciences Inc. (Arizona)	**X**		MolDX: DecisionDx-Melanoma (L37748) *(Applies to the indicated performing laboratory)*	
Decision DX-UM (Uveal melanoma)	84999, 0081U	Castle Biosciences Inc. (Arizona)	**X**		MolDX: DecisionDx-UM (Uveal Melanoma) (L37072) *(Applies to the indicated performing laboratory)* For services **prior to 01/01/2017**, DecisionDX-UM was non-covered according to Noridian LCD L35008.	
EndoPredict® Breast Cancer Gene Expression Test	81599, 81518	Myriad Genetics (Utah)	**X**		MolDX: EndoPredict® Breast Cancer Gene Expression Test (L37311) *(Applies to the indicated performing laboratory)*	
Envisia Genomic Classifier	81479	Veracyte, Inc., (California)	**X**		For services **on and after 5/27/2019**: ✓ MolDX: Envisia, Veracyte, Idiopathic Pulmonary Fibrosis Diagnostic Test (L37887) *(Applies to the indicated performing laboratory)* For services rendered **between 4/1 and 5/27/2019**: ✓ Use the Palmetto GBA LCD for MolDX: Envisia, Veracyte, Idiopathic Pulmonary Fibrosis	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					Diagnostic Test (L37857), as this would provide coverage criteria during the gap between when MolDX had available approved coverage and when the Noridian LCD was ready for the laboratory's service area. This allows members to receive potential coverage for the test in a more timely manner.	
ePlex Respiratory Pathogen (RP) Panel	0115U	GenMark Diagnostics (California)		**X**	MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37301) *(According to the LCD, "Multiplex PCR respiratory viral panels of 6 or more pathogens are non-covered.")*	
EXaCT-1 Whole Exome Test		Weill Cornell Medicine Clinical Genomics Laboratory			See row below for Whole Exome and Whole Genome Sequencing	
ExosomeDx® Prostate (IntelliScore) - also referred to as ExoDx®	0005U	Multiple		**X**	Biomarker Testing (Prior to Initial Biopsy) for Prostate Cancer Diagnosis (L37733) *(Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT) (See non-coverage of CPT 0005U in this LCD)* Billing and Coding: Biomarkers for Oncology (A52986) *(Laboratories in CO, NM, OK, TX, AK, LA, MS, DE, MD, NJ, PA) (See non-coverage of CPT 0005U in this LCA)*	
Familial Adenomatous Polyposis (FAP) (includes Attenuated FAP [AFAP]) and MUTYH-Associated	81201-81203, 81403, 81406, 81479	Any laboratory in the states of Washington, Oregon, Idaho, Utah, or California	**X**		MolDX: APC and MUTYH Gene Testing (L36884) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
Polyposis (MAP) (formerly MYH-associated polyposis) *(APC and MUTYH)*					MolDX: APC and MUTYH Gene Testing (L36882) *(Laboratories in CA and NV)*	
Fetal Chromosomal Aneuploidy (e.g., trisomy 21, monosomy X) and Fetal Chromosomal Microdeletion(s) (e.g., DiGeorge syndrome, Cri-du-chat syndrome) genomic sequence analysis **Examples:** • *Harmony™ Prenatal Test (Ariosa Diagnostics, a division of LabCorp)* • *InformaSeq℠ Prenatal Test (Integrated Genetics)* • *MaterniT Genome (Sequenom)* • *MaterniT21™ Plus (Sequenom Laboratories)* • *Panorama Prenatal Panel (Natera)*	81420, 81422, 81507, 0009M	Multiple		X	Molecular Pathology Procedures (L35000) *(Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, or VT) (Search for CPT code; Group 3 Codes are considered "not medically necessary.")* Biomarkers Overview (L35062) *(Laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA) (Search for CPT code)* For laboratories in all other states, ***or*** if a specific CPT code is not found in an LCD listed above, apply the following Medicare guidance: ✓ In order to be eligible for Medicare coverage, an item or service must fall within a statutory benefit category. In order to be paid under the diagnostic laboratory testing benefit, a diagnostic test must (1) not be considered screening (testing in the absence of clinical signs and symptoms of disease) and (2) must be ordered by a physician who is treating the beneficiary and who will use the tests results in the management of a beneficiary's specific medical problem. These tests are performed in the absence of clinical signs/symptoms, and	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
• *Panorama Extended Panel (Natera)* • *Prelude™ Prenatal Screen (Counsyl, Inc.)* • *Progenity Innatal Prenatal Screen (Progenity)* • *Verifi® Prenatal Test (Illumina, formerly Verinata Health)* • *VisibiliT (Sequenom)*					the test results are not used in the management of a beneficiary's specific medical problem. Therefore, these tests are not considered medically reasonable or necessary as they do not meet a Medicare benefit category and/or reasonable and necessary threshold for coverage, as required by the SSA §1862(a)(1)(A) and 42 CFR 410.32(a).	
FilmArray® Gastrointestinal (GI) Panel	0097U	BioFire Diagnostics (Salt Lake City, UT)	**X**		Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification Tests (NAATs) (L37368) *(This test includes more than 12 targets or organisms, and thus, according to the LCD, this test "will only be covered in critically ill or immunosuppressed patients." See the ICD-10 list in the LCD for additional assistance.)*	
FilmArray Respiratory Panel (RP) EZ	0098U	BioFire Diagnostics (Salt Lake City, UT)		X	MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37315) *(According to the LCD, "Multiplex PCR respiratory viral panels of 6 or more pathogens are non-covered.")*	
FilmArray Respiratory Panel (RP)	0099U	BioFire Diagnostics (Salt Lake City, UT)		X	MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37315) *(According to the LCD, "Multiplex PCR respiratory viral panels of 6 or more pathogens are non-covered.")*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met*		MEDICARE RATIONALE / REFERENCE Back to Criteria
			Yes	No	
FilmArray® Respiratory Panel 2 (RP2)	0100U	BioFire Diagnostics (Salt Lake City, UT)		X	MolDX: Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels (L37315) *(According to the LCD, "Multiplex PCR respiratory viral panels of 6 or more pathogens are non-covered.")*
FirstSight^{CRC}	0091U	CellMax Life (California)		**X**	NCD for Colorectal Cancer Screening Tests (210.3) *(Medicare benefits for colorectal cancer screening tests are limited to tests found in this NCD.)*
FISH (fluorescent in situ hybridization)	88271, 88273, 88274, 88275, 88291	Multiple	**X**		For ***myelodysplastic syndromes (MDS)***: ✓ MolDX: MDS FISH (L37602) *(Per the LCD, "Molecular NGS testing alone (for myeloid mutations) or in combination with FISH testing is not reasonable and necessary for the diagnosis of MDS, and is not a Medicare benefit.")*
FoundationOne® *(315 genes – too many to list)*	81479	Foundation Medicine, Inc. (Massachusetts or North Carolina)	**X**		N/A - Review of the laboratory's website indicates this test is no longer available. To review past services, use the following references as necessary: ✓ National Government Services Inc. (NGS) Retired LCD for Genomic Sequence Analysis Panels in the Treatment of Non-Small Cell Lung Cancer (L36376) *(Laboratories in MA, and for services **prior to** 4/1/2019)* ✓ RETIRED Palmetto GBA LCD for MolDX: NSCLC, Comprehensive Genomic Profile Testing (L36143) *(Laboratories in NC)*

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
FoundationOne CDx™ (F1CDx)	0037U or 81479 may be used. (Per Medicare Transmittal 215, CPT 81455 may have been used for claims between 3/16/18 and 3/31/18).	Foundation Medicine, Inc. (Massachusetts or North Carolina)	**X**		Next Generation Sequencing (NGS) (90.2) *(Page 11 of Transmittal 215 may help with diagnosis questions; however, general NCD criteria must still be met. The presence of an ICD-10 code does not in itself imply coverage. This test is on the FDA website as an approved companion diagnostic or in vitro test.)*	
FoundationOne® Heme *(Hematologic Malignancy Genomic Sequencing Assay)* *(405 genes – too many to list in full, but panel includes BLM and FANCC)*	81479	Foundation Medicine, Inc. (Massachusetts or North Carolina)	**X**		National Government Services Inc. (NGS) LCD for Genomic Sequence Analysis Panels in the Treatment of Hematolymphoid Diseases (L37606) *(Laboratories in MA) (This LCD allows coverage of panel testing of up to 50 genes. This FoundationOne® Heme panel has over 400 genes, and therefore, would not be eligible for coverage under this LCD. In addition, the NGS LCD L35000 considers panel testing over greater than 51 genes [81455] to be non-covered, and this same non-coverage rationale is applied to this FoundationOne® Heme test, even if reported with 81479.)* Certain single gene tests (i.e., *JAK2, CALR*, and *MPL*) may be medically necessary for an	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					individual. The clinical utility of several gene components in this panel has not been demonstrated, and most of the gene components of this test have been reviewed by MolDX and determined to not meet Medicare's requirements for coverage [e.g., *BLM* and *FANCC*]. 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). *(Laboratories in NC)*	
GeneSight® ADHD Test *(CYP2D6, COMT, and ADRA2A)*	81479 or 81599	AssureRx Health, Inc. (Mason, OH)		**X**	When performed ***with GeneSight® Psychotropic Panel*** *(Applies to the indicated performing laboratory)*: ✓ The only gene component in the GeneSight® ADHD Test that may be eligible for coverage (*CYP2D6*) is already included in the GeneSight® Psychotropic Panel test. Duplicate testing of this gene would not be medically reasonable and necessary. The remaining genes of the GeneSight® ADHD Test (*COMT* and *ADRA2A*) are not considered reasonable and necessary and are listed as "Non-Covered test" on the CGS Excluded Test list. Therefore, the GeneSight® ADHD panel test is not medically reasonable or necessary when performed with the GeneSight® Psychotropic Panel test.	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					When performed ***alone***: ✓ This panel consists of three (3) gene tests, and only a portion of the GeneSight® ADHD panel test *may* be medically reasonable or necessary under Sec. 1862(a)(1)(A), but only when specified criteria are met. For treatment of ADHD, it would not be expected to meet these requirements due to the gene components ADRA2A and COMT being considered "noncovered" tests (per the see the LCD attachment for L36021, "Non-Covered tests" list) and the ***CYP2D6 component*** only being considered medically necessary when specific criteria are satisfied (per LCD L35332).[15,16]	
GeneSight® Analgesic Panel *(CYP1A2, CYP2B6, CYP3A4, CYP2C19, CYP2C9, CYP2D6, OPRM1)*	81599	AssureRx Health, Inc. (Mason, OH)		**X**	When performed ***with GeneSight® Psychotropic Panel*** *(Applies to the indicated performing laboratory)*: ✓ The GeneSight® Analgesic Panel is not considered medically reasonable and necessary when performed with the GeneSight® Pyschotropic Panel because the Analgesic Panel is a duplication of all but one gene in the Psychotropic Panel test. The duplicate testing of genes *CYP2D6, CYP2C19, CYP2C9, CYP3A4, CYP2B6*, and *CYP1A2* that make up the GeneSight® Analgesic panel would not be	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					considered reasonable or necessary under Medicare because they would already be considered under a separate test. The only gene component not duplicated is the OPRM1 gene test, which is listed as a "Non-Covered test" on the CGS Excluded Test list. Therefore, the GeneSight® Analgesic panel test is not medically reasonable or necessary under Sec. 1862(a)(1)(A) when performed with the GeneSight® Pyschotropic Panel test. When performed ***alone***: ✓ See coverage decision for the gene CYP2B6 in Table 2 above.	
GeneSight® MTHFR Test	81291	AssureRx Health, Inc. (Mason, OH)			Since this is a single gene test, see M-GT20 for MTHFR testing	
GeneSight® Psychotropic Genetic Panel *(CYP1A2, CYP2B6, CYP3A4, CYP2C19, CYP2C9, CYP2D6, SLC6A4, HTR2A)*	81479	AssureRx Health, Inc. (Mason, OH)	**X**		CGS Administrators LCD for MolDX: GeneSight® Assay for Refractory Depression (L35443)[15,16] *(Applies to the indicated performing laboratory)*	
GeneTrails® AML/MDS Genotyping Panel *(42 genes – too many to list individually, but it does*	81450	OHSU Knight Diagnostics Laboratories (Portland, OR)	**X**		Noridian J-F LCD for MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36186) *(Applies to the indicated performing laboratory)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
include ABL, MPL, CALR, and JAK2 exon 12 testing)						
GeneTrails® Comprehensive Solid Tumor Panel *(124 genes – too many to list)*	81445	OHSU Knight Diagnostics Laboratories (Portland, OR)	**X**		For ***Lynch Syndrome***: ✓ Noridian J-F LCD for MolDX: Genetic Testing for Lynch Syndrome (L36374) *(Applies to the indicated performing laboratory) (See non-coverage of CPT 81445 in this LCD)* For ***BRCA-related conditions (e.g., breast or ovarian cancers)***: ✓ Noridian J-F LCD for MolDX: BRCA1 and BRCA2 Genetic Testing (L36163) *(Applies to the indicated performing laboratory) (See non-coverage of panels which include genes not relevant to individual personal history in this LCD. See also the LCA A54898 which reads, "The inclusion of genes without specific proven clinical utility for a particular disease is either screening or considered research/investigational, and as such, is not a Medicare benefit.")* For ***all other indications***: ✓ Certain *single gene* tests (i.e., *BRCA1/2*) may be medically necessary for an individual. The clinical utility of several gene components in this panel has not been demonstrated, and some of the gene	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					components of this test have been reviewed by MolDX and determined to not meet Medicare's requirements for coverage. Therefore, this test is considered not medically reasonable or necessary according to the Palmetto GBA MolDX Program, and the Social Security Act, §1862(a)(1)(A) unless noted as covered for a certain indication in an LCD above. See also the LCA A54898 which reads, "The inclusion of genes without specific proven clinical utility for a particular disease is either screening or considered research/investigational, and as such, is not a Medicare benefit.") *(Applies to the indicated performing laboratory)*	
GeneTrails® Solid Tumor Fusion Gene Panel *(20 genes – too many to list)*	81445	OHSU Knight Diagnostics Laboratories (Portland, OR)	**X**		For ***Lynch Syndrome***: ✓ Noridian J-F LCD for MolDX: Genetic Testing for Lynch Syndrome (L36374) *(Applies to the indicated performing laboratory) (See non-coverage of CPT 81445 in this LCD)* For ***BRCA-related conditions (e.g., breast or ovarian cancers)***: ✓ Noridian J-F LCD for MolDX: BRCA1 and BRCA2 Genetic Testing (L36163) *(Applies to the indicated performing laboratory) (See non-coverage of panels which include*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					genes not relevant to individual personal history in this LCD. See also the LCA A54898 which reads, "The inclusion of genes without specific proven clinical utility for a particular disease is either screening or considered research/investigational, and as such, is not a Medicare benefit.")) For ***all other indications***: ✓ Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual. The clinical utility of several gene components in this panel has not been demonstrated, and some of the gene components of this test have been reviewed by MolDX and determined to not meet Medicare's requirements for coverage (e.g., VEGFR2, DDR2, FGFR1, FGFR3, GNA11, GNAQ, GNAS, MAP2K1, MET, NOTCH1, NF1, RB1, STK11, TSC1, and TSC2). 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) unless noted as covered for a certain indication in an LCD above. *(Applies to the indicated performing laboratory)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
Guardant360 Panel *(73 genes – too many to list)*	81201, 81210, 81235, 81270, 81272, 81275, 81293, 81310, 81311, 81314, 81321, 81400, 81401, 81402, 81403, 81404, 81405, 81406, and/or 81479	Guardant Health, Redwood City, CA	**X**		Noridian J-E LCD for MolDX: Guardant360® Plasma-Based Comprehensive Genomic Profiling in Non-Small Cell Lung Cancer (NSCLC) (L37649) *For services rendered between 8/27/2018 and 10/20/2018, use the Palmetto LCD L37699. For services prior to 8/27/2018, coverage had not yet been approved by the MolDX contractor so payment cannot be made per the LCD L35160 which states, reimbursement will be allowed only for "approved tests covered for dates of service consistent with the effective date of the coverage determination."*	
GYNplus *(BRCA1, BRCA2, BRIP1, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, PTEN, RAD51C, RAD51D, and TP53)* ***With or without the +RNAinsight™ for GynPlus® add-on test***	81479, 0135U	Ambry Genetics (Aliso Viejo, CA)		**X**	Noridian J-E LCD for MolDX: BRCA1 and BRCA2 Genetic Testing (L36161) *(Applies to the indicated performing laboratory)* *(The LCD requires all genes included in a panel test to be relevant to the individual being tested; however, some genes in this panel have been determined to be excluded genetic tests [e.g., TP53]. When genes are included in a panel that have been determined to be excluded from Medicare coverage, the panel as a whole cannot be considered medically reasonable or necessary under Palmetto GBA MolDX Program, and the Social Security Act, §1862(a)(1)(A). See also the LCA A54897 which reads, "The inclusion of genes without specific proven clinical utility for a particular disease is either screening or considered research/investigational, and as such, is not a*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					Medicare benefit.") **Note:** As an add-on code for *the GynPlus* test, +RNAinsight™ for GynPlus® by Ambry Genetics (0135U) is also non-covered if performed.	
HCMFirst *(MYBPC3 and MYH7)*	81479	Ambry Genetics (Aliso Viejo, CA)		**X**	LCD attachment for L35160, Excluded Test List – as of 08/01/2016 *(Applies to the indicated performing laboratory) (Panel tests which exclusively consist of non-covered gene components are not medically reasonable and necessary under Medicare coverage guidelines. Both of the gene components of this panel are excluded or non-covered gene tests.)*	
HeproDX™	0006M	GoPath Laboratories, LLC.		**X**	LCD attachment for L36256, Excluded Test List – as of 08/01/2016 *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* LCD attachment for L35160, Excluded Test List – as of 08/01/2016 *(Laboratories in CA and NV)*	
Hereditary cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy), genomic sequence analysis panels	81439	Multiple		**X**	Molecular Pathology Procedures (L35000) *(Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, VT) (Search for CPT code)* Biomarkers Overview (L35062) *(Laboratories in CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA) (Search for CPT code)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met*		MEDICARE RATIONALE / REFERENCE	Back to Criteria
			Yes	No		
HERmark	81479	LabCorp	X		MolDX: HERmark® Assay by Monogram Billing and Coding Guidelines (A54439) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* MolDX: HERmark® Assay by Monogram Billing and Coding Guidelines (A54437) *(Laboratories in CA and NV)*	
HHTFirst *(ACVRL1, ENG, SMAD4)*	81479	Ambry Genetics (Aliso Viejo, CA)			N/A - Review of the laboratory's website indicates this test is no longer available.	
HHTNext *(ACVRL1, ENG, SMAD4, GDF2, RASA1)*	81479	Ambry Genetics (Aliso Viejo, CA)		X	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. MolDX has determined panels may be denied as "not medically necessary" when certain non-covered gene tests (see Table 2) are included because they do not meet Medicare's medical necessity requirements. This panel is "not medically necessary" because it includes at least one of these specific excluded gene tests from Table 2. *(The LCA for* MolDX: ENG and ACVRL1 Gene Tests Billing and Coding Guidelines (A55181) *may indicate potential coverage for ACVRL1 and/or ENG testing when a diagnosis has not yet been established for suspected HHT, but not all genes in this panel have satisfied the MolDX requirements for coverage. See also the* LCD attachment for L35160, Excluded Test List – as of 08/01/2016*, where SMAD4 and RASA1 are both listed as excluded tests.)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
HHTReflex *(ACVRL1, ENG, SMAD4 gene sequence analysis & deletion/duplication, with reflex to gene sequence analysis & deletion/duplication of GDF2 and RASA1 genes)*	81479	Ambry Genetics (Aliso Viejo, CA)			N/A - Review of the laboratory's website indicates this test is no longer available.	
INFINITI® Neural Response Panel *(ABCB1, COMT, DAT1, DBH, DOR, DRD1, DRD2, DRD4, GABA, GAL, HTR2A, HTTLPR, MTHFR, MUOR, OPRK1, OPRM1)*	0078U	PersonalizeDx Labs (Carlsbad, CA)		**X**	None of the gene components that make up this panel test are listed on the MolDX Approved Molecular Tests for Reimbursement web page on the Noridian website. Several of the gene components that make up this panel are actually noted as non-covered gene tests on the LCD attachment for L35160, Excluded Test List – as of 08/01/2016 (*ABCB1, COMT, DRD1, DRD2, DRD4, HTR2A, MTHFR, OPRK1, OPRM1*). Also, the remaining gene components in this plan do not have a MolDX coverage determination, which implies they have not been reviewed for clinical utility/validity (*DAT1, DBH, DOR, GABA, GAL, HTTLPR, MUOR*), which also makes them non-covered until such evaluation by MolDX has been completed. Finally, diagnostic laboratory tests to determine *risk* for developing a condition are not covered under Medicare and *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	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					necessary for the diagnosis and treatment of illness or injury...". *(All information applies to the indicated performing laboratory)*	
InvisionFirst™ - Lung (aka InVision)	81479	Inivata (North Carolina)	**X**		MolDX: Inivata, InVisionFirst, Liquid Biopsy for Patients with Lung Cancer (L37870)	
InVitae Assay	Varies by gene tested or 81479	InVitae Corp.(San Francisco, CA)		**X**	If any gene in Table 2 is part of the panel: ✓ Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. MolDX has determined panels may be denied as "not medically necessary" when certain non-covered gene tests (see Table 2) are included because they do not meet Medicare's medical necessity requirements. This panel is "not medically necessary" because it includes at least one of these specific excluded gene tests from Table 2. If a gene from Table 2 is **not** a component of the panel performed test, one of the following references may apply: ✓ MolDX: BRCA1 and BRCA2 Genetic Testing (L36161) *Applies to the indicated laboratory) LCD L36161 requires all genes included in a panel be relevant to the individual being tested.*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					✓ MolDX: Genetic Testing for Lynch Syndrome L36370 *(Applies to the indicated laboratory)*	
Integrated BRACAnalysis®	81162	Myriad Genetics (Utah)	**X**		MolDX: BRCA1 and BRCA2 Genetic Testing (L36163) *(Applies to the indicated performing laboratory)*	
KidneyIntelX™	0105U	RenalytixAI (MD and NY)		**X**	The KidneyIntelX™ test is used to identify individuals most likely to experience fast-progressing kidney disease. The results are not used to diagnose or make direct treatment decisions for an illness or injury, as required for Medicare under the *Social Security Act, §1862(a)(1)(A)*. Therefore, this test is considered not medically necessary.	
LVNCNext™ *(ACTC1, LDB3/ZASP, LMNA, MYBPC3, MYH7, TAZ, TNNT2 TPM1)*	81479	Ambry Genetics (Aliso Viejo, CA)		**X**	LCD attachment for L35160, Excluded Test List – as of 08/01/2016 *(Applies to the indicated performing laboratory) (Panel tests which exclusively consist of non-covered gene components are not medically reasonable and necessary under Medicare coverage guidelines.)*	
Lymph3Cx Lymphoma Molecular Subtyping Assay	0120U	Mayo Clinic Laboratory (Arizona)		**X**	**Arizona**: • 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 LCA A54554)* • The Noridian LCD L36256 states reimbursement is only allowed for "approved	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review. • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • This test does not have a coverage policy available. Therefore, it is not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MolDX review is complete and coverage is indicated by MolDX or Noridian. **Minnesota**: According to the LCD for *Molecular Pathology Procedures* (L35000), gene expression profiling for certain cancers is listed as a type of test that may not be covered. **Florida**: The LCD for *Molecular Pathology Procedures* (L34519) includes the same note as that mentioned above.	
Lynch Syndrome (LS) genetic panel tests *(any panel test for LS that includes, but may not be limited to, the BRAF V600E,*	81210, 81288, 81292, 81293, 81294, 81295, 81296, 81297, 81298, 81299,	Any laboratory in the states of Washington, Oregon, Idaho,	**X**		MolDX: Genetic Testing for Lynch Syndrome (L36374) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY) (Until 4/16/2019, see also the LCD L35024 for potential additional indications. As*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
MLH1, MSH2, MSH6, PMS2, and/or EPCAM genes, performed in any of the states listed to the right)	81300, 81301, 81317, 81318, 81319, 81403, 81435, 81445, 81455, and/or 81479	Utah, California, or Florida			*of 4/16/2019, the LCD L36374 will be updated to align with L35024.)* MolDX: Genetic Testing for Lynch Syndrome L36370 *(Laboratories in CA and NV) (Until 4/16/2019, see also the LCD L35024 for potential additional indications. As of 4/16/2019, the LCD L36370 will be updated to align with L35024.)* Genetic Testing for Lynch Syndrome (L34912) *(Laboratories in FL)* *Microsatellite instability (MSI) and immunohistochemistry (IHC) testing may also be requested. The LCDs noted above all address MSI and IHC testing for Lynch Syndrome conditions as well.*	
Macula Risk® PGx *(CFH, ARMS2, CFI, C3, C2, CFB, LIPC, ABCA1, CETP, COL8A1, APOE, TIMP3)*	81401, 81479	Arctic Medical Laboratories (Grand Rapids, MI)		**X**	• 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). *(WPS LCA A55391)* • The Wisconsin Physician Services (WPS) LCD L36807 states reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process.	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					• This test is not considered medically reasonable and necessary until a MolDX review is complete and coverage is indicated by MolDX or WPS.	
MammaPrint® (aka, the "Amsterdam signature")	81521	Agendia (Irvine, CA)	**X**		Noridian J-E LCD for MolDX: MammaPrint Billing and Coding Guidelines (A54445) (Applies to the indicated performing laboratory)	
Fetal congenital abnormality biochemical assays with added Y chromosome test result **Examples:** • Maternal Fetal Screen | T1 + Y Chromosome℠ • Preeclampsia Screen | T1 + Y Chromosome℠ **Note:** *Biochemical* assays differ from *chromosomal* genomic sequencing assays reported with 81420, 81422, 81507, etc. See separate rows for chromosomal testing.	0126U, 0128U	Eurofins NTD, LLC		**X**	For Medicare members of child-bearing age, biochemical assays for the prenatal screening of fetal congenital abnormalities are currently allowed as medically necessary when reported with CPT codes 84163, 84704, 82105, 86336, 83520. Tests with the added component of fetal sex determination (Y chromosome) (0126U or 0128U) are **not** considered medically necessary under the *Social Security Act, §1862(a)(1)(A)*. Test options **without** this additional component should be used for Medicare members. Biochemical assays of analytes (free beta-hCG, PAPP-A, AFP, placental growth factor, and/or inhibin-A; 0124U, 0125U, 0127U) **without** the Y chromosome test results are not addressed by this medical policy and are considered **medically necessary**.	
Millennium PGT *(CYP2B6, OPRM1, CYP2C9, VKORC1, HLA-B, CYP2C19, CYP2D6, MTHFR, DRD2, HTR2C,*	81225, 81226, 81227, 81291, 81401, and/or 81479	Millennium Laboratories		**X**	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. MolDX has determined panels may be denied as "not medically necessary"	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
UGT2B15, COMT, CYP3A4, CYP3A5) *(Only when the complete panel test - if individual gene-drug tests are requested, see Cross References for single gene testing and apply gene-specific criteria)*					when certain non-covered gene tests (see Table 2) are included because they do not meet Medicare's medical necessity requirements. This panel is "not medically necessary" because it includes at least one of these specific excluded gene tests from Table 2. In addition, several of the genes in this panel are either not covered (e.g., MTHFR and OPRM1) or are only covered for limited indications (e.g., CYP2C9, VKORC1, CYP2C19, and CYP2D6). Therefore, this panel as developed is not medically necessary under Medicare.	
MI Profile™ *formerly, Target Now™*	81202, 81210, 81211, 81235, 81245, 81270, 81275, 81402, 81403, 81404, 81405, and/or 81479	Caris Life Science, Arizona	**X**		*The MI Profile panel includes several test techniques, including NGS, MSI, and IHC.* • *For the IHC components, the LCD for Special Histochemical Stains and Immunohistochemical Stains (L36353) addresses these tests, and with limited exception, most IHC testing does not have proven clinical utility. This LCD is used for CPT codes 88341, 88342, and 88360, if submitted. The MSI and dMMR LCD below may also be applicable for some scenarios.)* • *The NGS component is also known as the MI TumorSeek test and is addressed in the next row. This test may be allowed as medically necessary for certain indications; however, it is reviewed separately.*	
MI TumorSeek	81455 or 81479	Caris Life Science, Arizona	**X**		For ***BCR-ABL Negative Myeloproliferative Disease***:	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
	As indicated in their approval letter, MolDX determined CPT 81455 is the most appropriate code for this test. Therefore, this should be the code used.				✓ MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36186) For ***Lynch Syndrome***: ✓ MolDX: Genetic Testing for Lynch Syndrome (L36374) *(Search for CPT 81455)* For ***BRCA-related conditions***: ✓ MolDX: BRCA1 and BRCA2 Genetic Testing (L36163) *(See non-coverage of panels which include genes not relevant to individual personal history in this LCD. See also the LCA A54898 which reads, "The inclusion of genes without specific proven clinical utility for a particular disease is either screening or considered research/investigational, and as such, is not a Medicare benefit.")* For ***lung cancer, including NSCLC***: NCD 90.2 states any NGS test not addressed by the NCD is addressed by the local contractors. However, the LCD for NSCLC by the local contractor Noridian was retired last September. Therefore, until new LCDs are developed, apply the following:	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					Retired MolDX: NSCLC, Comprehensive Genomic Profile Testing (L36198)	
MicroGenDX qPCR & NGS For Infection	0112U	MicroGenDX	**X**		Molecular Diagnostics: Genitourinary Infectious Disease Testing (L35015) ✓ If signs/symptoms exist, and there is suspicion of an infectious disease that would directly warrant and prompt testing for the detection of a candida species, then the test may be considered medically necessary. ✓ If performed in the absence of signs or symptoms, even for an immune compromised patient, then it may be considered screening.	
Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) biomarker testing *Testing may be performed for various solid tumors, including but not limited to, metastatic melanoma, non-small cell lung cancer, recurrent or metastatic head and neck squamous cancer, advanced/metastatic urothelial cancer and classical Hodgkin's lymphoma*	81301, 81479, 88341, 88342	Multiple	**X**		MolDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker Billing and Coding Guidelines for Patients with Unresectable or Metastatic Solid Tumors (A56104) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* MolDX: Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker Billing and Coding Guidelines for Patients with Unresectable or Metastatic Solid Tumors (A56103) (*Laboratories in CA and NV)* **Note:** This testing is sometimes performed via multi-gene NGS panels which also include MSI or dMMR testing using immunohistochemistry (IHC).	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					Some LCDs address this approach within them (e.g., the LCD for Lynch Syndrome).	
MiPS (Mi-Prostate Score)	0113U	MLabs (Ann Arbor, MI)		**X**	• 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). *(WPS LCA A55391)* • The Wisconsin Physician Services (WPS) LCD L36807 states reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • This test is not considered medically reasonable and necessary until a MolDX review is complete and coverage is indicated by MolDX or WPS. • Note the LCD L37733 for additional Medicare jurisdictions also addresses the test and also considers it non-covered.	
Mitochondrial Nuclear Gene Tests	81440 or 81479	Multiple		**X**	MolDX: Mitochondrial Nuclear Gene Tests Billing and Coding Guidelines (A55291) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* MolDX: Mitochondrial Nuclear Gene Tests Billing and Coding Guidelines (A55290) (*Laboratories in CA and NV))*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	COVERAGE AVAILABLE? *When criteria met* No	MEDICARE RATIONALE / REFERENCE Back to Criteria
Molecular Microscope® MMDx—Heart	0087U	Kashi Clinical Laboratories (Portland, OR) Kashi website states, "Testing services performed by authorized laboratories under a sublicense from One Lambda, Inc., a part of Thermo Fisher Scientific." Thermo Fisher Scientific is headquartered in Waltham, MA, but may have labs in OR, CA, and UT.		**X**	• 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 LCA A54554)* • The Noridian LCD L36256 states reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review. • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • Unlike the AlloMap test, this test does not have a coverage policy available. Therefore, it is not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MolDX review is complete and coverage is indicated by MolDX or Noridian.
Molecular Microscope® MMDx—Kidney	0088U	Kashi Clinical Laboratories (Portland, OR) Kashi website states, "Testing services performed by authorized		**X**	• 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 LCA A54554)* • The Noridian LCD L36256 states reimbursement is only allowed for "approved

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
		laboratories under a sublicense from One Lambda, Inc., a part of Thermo Fisher Scientific." Thermo Fisher Scientific is headquartered in Waltham, MA, but may have labs in OR, CA, and UT.			tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review. • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • Unlike the AlloSure test, this test does not have a coverage policy available. Therefore, it is not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MolDX review is complete and coverage is indicated by MolDX or Noridian.	
MSK-IMPACT™		Memorial Sloan Kettering Cancer Center	**X**		Next Generation Sequencing (NGS) (90.2) *(This test is on the FDA website as an approved nucleic acid-based test.)*	
MYCODART Dual Amplification Real Time PCR Panels *MYCODART Dual Amplification Real Time PCR Panel for 6 Candida species* *MYCODART Dual Amplification Real Time PCR Panel for 4 Aspergillus species*	0068U, 0109U	RealTime Laboratories, Inc. (TX)	**X**		Molecular Diagnostics: Genitourinary Infectious Disease Testing (L35015) ✓ If signs/symptoms exist, and there is suspicion of an infectious disease that would directly warrant and prompt testing for the detection of a candida species, then the test may be considered medically necessary. ✓ If performed in the absence of signs or symptoms, even for an immune compromised patient, then it may be considered screening.	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
Myelodysplastic Syndrome (MDS) Diagnosis Panels *(any NGS panel to diagnose MDS, with or without FISH testing)*	Varies	Multiple		**X**	For ***myelodysplastic syndromes (MDS)***: ✓ MolDX: MDS FISH (L37602) *(Per the LCD, "Molecular NGS testing alone (for myeloid mutations) or in combination with FISH testing is not reasonable and necessary for the diagnosis of MDS, and is not a Medicare benefit.")*	
myPath Melanoma Assay	81479, 0090U	Myriad Genetics (Utah)	**X**		For services rendered ***prior to 04/29/2019***: ✓ Noridian LCD L36256 states reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX reviews the test. The MolDX effective date of coverage is 04/29/2019, and therefore, this test is considered not medically necessary prior to this date. For services rendered ***from 04/29/2019 through 06/02/2019***: ✓ MolDX: myPath Melanoma Assay (L37859) For services rendered ***on or after 06/03/2019***: ✓ MolDX: myPath Melanoma Assay (L37881)	
MyPRS™	81479	Signal Genetics LLC, (Little Rock, AR)	**X**		Biomarkers for Oncology (L35396)[16-18] (Applies to the indicated performing laboratory) *See the guideline specific to MyPRS™ found within the LCD.*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
myRisk® *(BRCA1, BRCA2, MLH1, MSH2, MSH6, PMS2, EPCAM, APC, MUTYH, CDKN2A, CDK4, TP53, PTEN, STK11, CDH1, BMPR1A, SMAD4, PALB2, CHEK2, ATM, NBN, BARD1, BRIP1, RAD51C, RAD51D, POLD1, POLE, GREM1)*	81162, 81211, 81213, and 81479	Myriad Genetics (Utah)		**X**	MolDX: BRCA1 and BRCA2 Genetic Testing (L36161) *(Applies to the indicated performing laboratory)* *(The LCD requires all genes included in a panel test to be relevant to the individual being tested. In addition, some genes in this panel have been determined to be excluded genetic tests [e.g., CDH1 and TP53]. When genes are included in a panel that have been determined to be excluded from Medicare coverage, the panel as a whole cannot be considered medically reasonable or necessary under Palmetto GBA MolDX Program, and the Social Security Act, §1862(a)(1)(A)). Also, tests to determine risk for developing a disease or condition are considered "screening" and therefore, are not eligible for Medicare coverage. Finally, see also the LCA A54898 which reads, "The inclusion of genes without specific proven clinical utility for a particular disease is either screening or considered research/investigational, and as such, is not a Medicare benefit.")*	
myTAI$_{HEART}$ test	0055U	TAI Diagnostics, Inc. (Wauwatosa, WI)		**X**	Molecular Pathology Procedures (L35000) *(This LCD states, "Testing assay(s) are Food and Drug Administration (FDA) approved/cleared or if LDT (lab developed test) or LDT protocol or FDA modified test(s) the laboratory documentation should support assay(s) of analytical validity and clinical*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					utility." While this LCD states the AlloMap test may be considered medically necessary, the myTAI$_{HEART}$ is not noted to have established analytical validity or clinical utility in this LCD. Therefore, this test is not medically reasonable or necessary.)	
Next Generation Sequencing panel tests not otherwise specified in the policy	Varies	Multiple	**X**		Next Generation Sequencing (NGS) (90.2) **Note:** This NCD is applied to NGS tests for cancer, and only if the test has FDA approval or clearance as a companion in vitro diagnostic test. To determine if a test has FDA approval, use the following sites (be sure to check all references, as some tests are only listed in one location): List of Cleared or Approved Companion Diagnostic Devices (In Vitro and Imaging Tools) Nucleic Acid Based Tests (be sure to check both the "Human Genetic Tests" tab and the "Microbial Tests" tab) For laboratory developed tests (LDT) without FDA approval, LCDs and LCAs will need to be used.	
Non-Small Cell Lung Cancer (NSCLC) comprehensive genomic profiling (CGP) *(Per LCD, CGP is defined as a single test using tumor tissue only)*					See row above for Comprehensive Genomic Profile Testing for Non-Small Cell Lung Cancer (NSCLC)	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
NSD1 Testing *(when performed as a panel test)*	81479 (panel use, but may also be seen with multiple units of 81403, 81405 and/or 81406)	Any laboratory in the states of Washington, Oregon, Idaho, Utah, or California		**X**	MolDX: NSD1 Gene Tests Billing and Coding Guidelines (A55615) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* *(See also the Noridian J-E LCA for MolDX: NSD1 Gene Tests Billing and Coding Guidelines (A55609) for laboratories located in California)*	
OncoGeneDx: BRCA1/BRCA2 Sequencing, Deletion and Duplication Analysis *(BRCA1, BRCA2)*	81211, 81213, and/or 81479	GeneDx Inc. (Gaithersburg, MD)	**X**		BRCA1 and BRCA2 Genetic Testing (L36715) [16-18] *(Applies to the indicated performing laboratory)*	
OncoGeneDx: Breast Cancer High Risk Panel *(BRCA1, BRCA2, CDH1, PTEN, STK11, TP53)*	81211, 81213, 81321, 81406, and/or 81479	GeneDx Inc. (Gaithersburg, MD)	**X**		BRCA1 and BRCA2 Genetic Testing (L36715) [16-18] *(Applies to the indicated performing laboratory) See the guidelines specific to "**Multigene Panels Indications**" and "**Limitations**" found in the LCD.*	
Oncomine™ Dx Target Test *Approved by FDA as a companion diagnostic test "to aid in the selection of NSCLC patients for treatment with targeted therapies, including:* • *IRESSA® (gefitinib) for EGFR L858R and Exon 19 deletions,*	0022U	Thermo Fisher Scientific (headquartered in Waltham, MA, but may have labs in OR, CA, and UT)	**X**		Next Generation Sequencing (NGS) (90.2) *(See also the MolDX: ThermoFisher Oncomine Dx Target Test For Non-Small Cell Lung Cancer Billing and Coding Guidelines (A55888), which applies to laboratories in all locations) (Page 11 of Transmittal 215 may help with diagnosis questions; however, general NCD and LCA criteria must still be met. The presence of an ICD-10 code does not in itself imply coverage. This test is on the FDA website as an approved nucleic acid-based test.)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
• *Tafinlar + Mekinist® (dabrafenib in combination with trametinib) for BRAF V600E, or* • *XALKORI® (crizotinib) for ROS1 fusion."*						
OncoTarget™/OncoTreat™	0019U	Columbia University Department of Pathology & Cell Biology / Darwin Health	**X**		Molecular Pathology Procedures (L35000) *(According to this LCD, "Any genetic test reported with a CPT code, not listed above or below, is subject to individual review." Therefore, individual review would need to be performed and until specific guidance is given for this test, clinical documentation must detail how the test results will directly impact treatment, outcome and/or clinical management in the care of the beneficiary. According to the laboratory's website, "While DarwinOncoTarget™ is available for all human malignancies, DarwinOncoTreat™ is currently available only for specific tumor subtypes for which the experimental assessment has already been completed (currently, breast carcinoma, glioblastoma multiforme, meningioma, neuroendocrine tumors, and sarcomas). Additional tumor subtypes will be added as the experimental validation data becomes available.")*	
Oncotype DX® AR-V7 Nuclear Detect	81479	Genomic Health (Redwood City, CA)	**X**		MolDX: Oncotype DX AR-V7 Nucleus Detect for Men with Metastatic Castrate Resistant Prostate Cancer (MCRPC) (L37746) *(Applies to the indicated performing laboratory)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met*		MEDICARE RATIONALE / REFERENCE	Back to Criteria
			Yes	No		
Oncotype DX® Breast Cancer Assay	81479, 81519	Genomic Health (Redwood City, CA)	**X**		MolDX: Oncotype DX® Breast Cancer Assay Billing and Coding Guidelines (A54480) *(Applies to the indicated performing laboratory)*	
Oncotype DX® Breast Cancer for DCIS	81479, 0045U	Genomic Health (Redwood City, CA)	**X**		MolDX: Oncotype DX® Breast Cancer for DCIS (Genomic Health™) (L36941) *(Applies to the indicated performing laboratory)*	
Oncotype DX® Colon Cancer Assay	81525	Genomic Health (Redwood City, CA)	**X**		MolDX: Oncotype DX® Colon Cancer Coding and Billing Guidelines (A54484) *(Applies to the indicated performing laboratory)*	
Oncotype DX® Genomic Prostate Score	81479	Genomic Health (Redwood City, CA)	**X**		MolDX: Oncotype DX® Genomic Prostate Score for Men with Favorable Intermediate Risk Prostate Cancer (L37305) *(Applies to the indicated performing laboratory)*	
Oncotype DX® Prostate Cancer Assay	81479, 0047U	Genomic Health (Redwood City, CA)	**X**		MolDX: Genomic Health™ Oncotype DX® Prostate Cancer Assay (L36364) *(Applies to the indicated performing laboratory)*	
OneOme RightMed Pharmacogenomic Test	0015U	OneOme, LLC (Minnesota)		**X**	Molecular Pathology Procedures (L35000) *(Applies to the indicated performing laboratory).* *According to this LCD, coverage for panel tests is limited to only the genes or test that are reasonable and necessary to obtain necessary information for therapeutic decision making. This panel test includes several non-covered genes under this LCD (e.g., CYP3A4, CYP3A5, DPYD, SLCO1B1, F2, F5, etc.), and for those gene tests that may have coverage available, coverage is limited to only certain indications. Therefore, this panel as a whole is considered not medically reasonable or necessary under Medicare.*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
OvaNext *(24 genes - ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, DICER1, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, SMARCA4, STK11, TP53)* ***With or without the +RNAinsight™ for OvaNext® add-on test***	81479, 0103U, 0132U	Ambry Genetics (Aliso Viejo, CA)		**X**	MolDX: BRCA1 and BRCA2 Genetic Testing (L36161) (Applies to the indicated performing laboratory) *(The LCD requires all genes included in a panel test to be relevant to the individual being tested. In addition, some genes in this panel have been determined to be excluded genetic tests [e.g., CHEK2 and STK11]. When genes are included in a panel that have been determined to be excluded from Medicare coverage, the panel as a whole cannot be considered medically reasonable or necessary under Palmetto GBA MolDX Program, and the Social Security Act, §1862(a)(1)(A). See also the LCA A54897 which reads, "The inclusion of genes without specific proven clinical utility for a particular disease is either screening or considered research/investigational, and as such, is not a Medicare benefit.")*	
PancNext *(APC, ATM, BRCA1, BRCA2, CDKN2A, EPCAM, MLH1, MSH2, MSH6, PALB2, PMS2, STK11, TP53)*	81479	Ambry Genetics (Aliso Viejo, CA)		**X**	MolDX: BRCA1 and BRCA2 Genetic Testing (L36161) (Applies to the indicated performing laboratory) *(The LCD requires all genes included in a panel test to be relevant to the individual being tested. In addition, some genes in this panel have been determined to be excluded genetic tests [e.g., STK11]. When genes are included in a panel that have been determined to be excluded from Medicare coverage, the panel as a whole cannot be considered medically reasonable or necessary under Palmetto GBA MolDX Program, and the Social Security Act, §1862(a)(1)(A)). Also, tests to*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					determine risk *for developing a disease or condition are considered "screening" and therefore, are not eligible for Medicare coverage. Finally, see also the LCA A54897 which reads, "The inclusion of genes without specific proven clinical utility for a particular disease is either screening or considered research/investigational, and as such, is not a Medicare benefit.")*	
Percepta© Bronchial Genomic Classifier	81479	Veracyte, Inc., South San Francisco, CA	**X**		MolDX: Percepta© Bronchial Genomic Classifier (L36886) *(Applies to the indicated performing laboratory)*	
Pervenio™ Lung NGS *(25 genes – too many to list)*	81210, 81235, 81275, 81321, 81400, 81401, 81403, 81404, 81405, and/or 81479	Life Technologies™ (Sacramento, CA)	**X**			
Pharmacogenetic panel tests *(CYP2C19, F2, F5, MTHFR, SLCO1B1, APOE)*	81225, 81240, 81241, 81291, 81400, 81401	Boston Heart Diagnostics	**X**		Molecular Pathology Procedures (L35000) *(Applies to the indicated performing laboratory) Only one listed gene test may be medically necessary under Medicare (CYP2C19, CPT 81225),* ***and*** *coverage is limited to only certain indications. All remaining genes are non-covered under this LCD (MTHFR, SLCO1B1, F2, F5, and APOE). Therefore, this panel test as a whole is considered not medically reasonable or necessary under Medicare.* See the guideline specific to each gene or CPT code within the LCD for further information.	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met*		MEDICARE RATIONALE / REFERENCE Back to Criteria
			Yes	No	
Pharmacogenetic panel tests *(pharmacogenomic panel tests which include genes CYP2C19, CYP2D6, CYP2C9, and/or VKORC1, when performed in the state listed to the right)*	Various	Florida	**X**		CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L35698) *(Laboratories in FL)*
Pharmacogenetic panel tests *(pharmacogenomic panel tests which include genes CYP2C19, CYP2D6, CYP2C9, and/or VKORC1, when performed in the one of the states listed to the right)*	Various	Any laboratory in the states of Washington, Oregon, Idaho, Utah, or California	**X**		MolDX: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L36312) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* MolDX: CYP2C19, CYP2D6, CYP2C9, and VKORC1 Genetic Testing (L36310) *(Laboratories in CA and NV).*
Pigmented Lesion Assay (PLA)	0089U	DermTech (California)		**X**	• 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 LCA A54552)* • The Noridian LCD L35160 states reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review. • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • This test is not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MolDX review is complete and coverage is indicated by MolDX or Noridian.

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
Praxis™ Extended RAS Panel	0111U	Illumina, Inc.	**X**		Next Generation Sequencing (NGS) (90.2) *(This test is on the FDA website as an approved nucleic acid-based test.)*	
PreGen-Plus™		LabCorp			N/A - No longer offered	
Prolaris™ Prostate Cancer Genomic Assay	81541	Myriad Genetics (Utah)	**X**		**Effective 10/15/2015**: For ***Intermediate Risk Disease***: ✓ Noridian J-F LCD for MolDX: Prolaris™ Prostate Cancer Genomic Assay for Men with Favorable Intermediate Risk Disease (L37082) For ***Low Risk and Very Low Risk Disease:*** ✓ Noridian LCD for MolDX-CDD: Prolaris™ Prostate Cancer Genomic Assay (L36350) For services **prior to 10/15/2015**, Prolaris was non-covered according to the Noridian LCA A52886 (use the Medicare Coverage Database (MCD) Archive site to find this now-Retired LCA).	
ProMark Risk Score	81479	Metamark Genetics	**X**		MolDX: ProMark Risk Score (L36706)	
PROMETHEUS® IBD sgi Diagnostic® Test	81479 (May also include 82397, 83520, 86140, 88346, and/or 88350)	Prometheus Laboratories (San Diego, CA)		**X**	MolDX: Prometheus IBD sgi Diagnostic Policy (L37299) *(Applies to the indicated performing laboratory)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
Prosigna Breast Cancer Assay	81520	LabCorp (when performed in the states of Washington, Oregon, Idaho, Utah, California, or North Carolina) or NanoString Technologies (Seattle, WA)	**X**		MolDX: Breast Cancer Assay: Prosigna (L36386) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* MolDX: Breast Cancer Assay: Prosigna (L36125) *(Laboratories in NC, SC, VA, WV, AL, TN, or GA)* MolDX: Breast Cancer Assay: Prosigna (L36380) *(Laboratories in CA and NV).*	
Prostate Gene Expression Profile		Clarient, Inc.			N/A - No longer offered	
ProstateNext® ***With or without the +RNAinsight™ for ProstateNext® add-on test***	0133U	Ambry Genetics (Aliso Viejo, CA)		**X**	MolDX: BRCA1 and BRCA2 Genetic Testing (L36161) (Applies to the indicated performing laboratory) *(The LCD requires all genes included in a panel test to be relevant to the individual being tested. In addition, some genes in this panel have been determined to be excluded genetic tests [e.g., CHEK2 and STK11]. When genes are included in a panel that have been determined to be excluded from Medicare coverage, the panel as a whole cannot be considered medically reasonable or necessary under Palmetto GBA MolDX Program, and the Social Security Act, §1862(a)(1)(A). See also the LCA A54897 which reads, "The inclusion of genes without specific proven clinical utility for a particular disease is either screening or considered research/investigational, and as such, is not a Medicare benefit.")* **Note:** As an add-on code for	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					the ProstateNext test, +RNAinsight™ for ProstateNext® by Ambry Genetics (0133U) is also non-covered if performed.	
Renaissance Rx Pharmacogenetic Analysis panel *(CYP2C19, CYP2C9, VKORC1, CYP2D6, CYP3A4, CYP3A5, F2, F5, MTHFR, OPRM1, UGT1A, UGT2B7)*	81225, 81226, 81227, 81401, and/or 81479	UTC Laboratories LLC. (New Orleans, LA)	**X**		Biomarkers Overview (L35062)) *(Applies to the indicated performing laboratory)* *The Novitas LCA A52986 states genes in a panel test are considered individually for medical necessity. Therefore, using LCD L35062, look for guidance specific to individual genes tested. For any gene **not** addressed in L35062, see the statement, "Biomarkers not addressed in this LCD or any other Novitas LCD will be considered not reasonable and necessary unless specifically covered by national policy."*	
RenalNext *(BAP1, EPCAM, FH, FLCN, MET, MITF, MLH1, MSH2, MSH6, PMS2, PTEN, SDHA, SDHB, SDHC, SDHD, TP53, TSC1, TSC2, VHL)*	81479	Ambry Genetics (Aliso Viejo, CA)		**X**	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. MolDX has determined panels may be denied as "not medically necessary" when certain non-covered gene tests (see Table 2) are included because they do not meet Medicare's medical necessity requirements. This panel is "not medically necessary" because it includes at least one of these specific excluded gene tests from Table 2.	
Reveal Lung Nodule Characterization	0092U	MagArray, Inc. (California)		**X**	• 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 LCA A54552)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					• The Noridian LCD L35160 states reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review. • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • This test is not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MolDX review is complete and coverage is indicated by MolDX or Noridian.	
Rosetta Cancer Origin Test™ *(Formerly miReview® mets²)*	81479	Rosetta Genomics (Philadelphia, PA)	**X**		Biomarkers for Oncology (L35396) *(Applies to the indicated performing laboratory) (See the guideline specific to the Rosetta Cancer Origin Test™ found within the LCD.)*	
RhythmFirst *(AKAP9, ANK2, CACNA1C, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, SCN4B, SCN5A, SNTA1)*	81479	Ambry Genetics (Aliso Viejo, CA)		**X**	LCD attachment for L35160, Excluded Test List – as of 08/01/2016 *(Applies to the indicated performing laboratory). (Panel tests which exclusively consist of non-covered gene components are not medically reasonable and necessary under Medicare coverage guidelines. All gene components of this panel test were reviewed and determined to not meet Medicare's reasonable and necessary requirements for coverage.)*	
RPS19 Testing *(when performed as a panel test)*	81479 (panel use, but may also be seen with multiple units of 81403 and/or 81405)	Any laboratory in the states of Washington, Oregon, Idaho, Utah, or California		**X**	MolDX: RPS19 Gene Tests Billing and Coding Guidelines (A55614) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* *(*MolDX: RPS19 Gene Tests Billing and Coding Guidelines (A55610) *(Laboratories in CA and NV)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
Thrombophilia and/or Hypercoagulability genetic panel tests *(any panel test for thrombophilia or hypercoagulability that includes **only** the F2, F5, and/or MTHFR genes, when performed in any of the states listed to the right)*	81240, 81241, 81291, and/or 81479	Any laboratory in the states of Washington, Oregon, Idaho, Utah, or California		**X**	MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) (L36159) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* MolDX: Genetic Testing for Hypercoagulability / Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) (L36155) *(Laboratories in CA and NV)*	
ThyGenX	81445		**X**		Biomarkers for Oncology (L35396)[16-18] *(Applies to the indicated performing laboratory) (See the guideline specific to ThyGenX found within the LCD. For testing frequency allowance and ICD-10 code guidance, see also the LCA A52986.)*	
ThyraMIR	0018U or 81479	*Interpace Diagnostics*	**X**		Biomarkers for Oncology (L35396)[16-18] *(Applies to the indicated performing laboratory) (See the guideline specific to ThyraMIR found within the LCD. For testing frequency allowance and ICD-10 code guidance, see also the LCA A52986.)*	
Thyroseq Genomic Classifier	0026U	CBLPath, Inc. & Univ of Pittsburgh Medical Center	**X**		Biomarkers for Oncology (L35396)[16-18] *(Applies to the indicated performing laboratory) (See the guideline specific to the ThyroSeq test found within the LCD. For testing frequency allowance and ICD-10 code guidance, see also the LCA A52986.)*	
TissueCypher® Barrett's Esophagus Assay	0108U	Cernostics (Pittsburg, PA)		**X**	Biomarkers for Oncology (L35396) (Applies to the indicated performing laboratory) *According to L35396, "Biomarkers not addressed in this LCD or*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					any other Novitas LCD will be considered not reasonable and necessary unless specifically covered by national policy."	
UW-OncoPlex	81455	University of WA		**X**	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. MolDX has determined panels may be denied as "not medically necessary" when certain non-covered gene tests (see Table 2) are included because they do not meet Medicare's medical necessity requirements. This panel is "not medically necessary" because it includes at least one of these specific excluded gene tests from Table 2.	
VeriStrat® assay	81538	Biodesix Inc., (Aurora, CO)	**X**		Biomarkers for Oncology (L35396) *(Applies to the indicated performing laboratory) (Use the guideline specific to the VeriStrat® assay found within the LCD. For ICD-10 code guidance, see also the LCA A52986.)*	
Viracor TRAC™ dd-cfDNA	0118U	Viracor Eurofins		**X**	• 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). *(WPS LCA A55391)* • The Wisconsin Physician Services (WPS) LCD L36807 states reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					• If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • This test is not considered medically reasonable and necessary until a MolDX review is complete and coverage is indicated by MolDX or WPS. • AlloSure and Prospera are similar dd-cfDNA tests. AlloSure has coverage criteria and Prospera has a draft LCD which is not yet final. Therefore, other tests are available with Medicare coverage established that can be considered.	
VistaSeq Breast Cancer Profile *(ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, FAM175A, MRE11A, MUTYH, NF1, NBN, PALB2, PTEN, RAD50, RAD51C, RAD51D, STK11 and TP53)*	81162, 81321, 81323, 81404, 81405, 81406, 81408, 81479	LabCorp (when performed in the states of Washington, Oregon, Idaho, Utah, California, or North Carolina)		**X**	✓ MolDX: BRCA1 and BRCA2 Genetic Testing (L36082) *(Applies to any laboratories in North Carolina)* ✓ MolDX: BRCA1 and BRCA2 Genetic Testing (L36163) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* ✓ MolDX: BRCA1 and BRCA2 Genetic Testing (L36161) *(Laboratories in CA and NV)* *All of the above LCDs require all genes included in a panel be relevant to the individual being tested. In addition, some genes in this panel have been determined to be excluded genetic tests [e.g., CDH1 and TP53]. When genes are included in a panel that have been determined to be excluded*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					from Medicare coverage, the panel as a whole cannot be considered medically reasonable or necessary under Palmetto GBA MolDX Program, and the Social Security Act, §1862(a)(1)(A)).	
VistaSeq Breast and GYN Cancer Profile *(ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, FAM175A, FANCC, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2, PTEN, RAD50, RAD51C, RAD51D, STK11 and TP53)*	81432	LabCorp (when performed in the states of Washington, Oregon, Idaho, Utah, California, or North Carolina)	**X**		✓ MolDX: BRCA1 and BRCA2 Genetic Testing (L36082) *(Applies to any laboratories in North Carolina)* ✓ MolDX: BRCA1 and BRCA2 Genetic Testing (L36163) *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* ✓ MolDX: BRCA1 and BRCA2 Genetic Testing (L36161) *(Laboratories in CA and NV)* *LCDs L36082, L36161, and L36163 require all genes included in a panel be relevant to the individual being tested. Therefore, coverage is only allowed when **all genes** will provide actionable information for clinical decision making.*	
VistaSeq Breast and GYN Cancer Profile *(ATM, BARD1, BRCA1, BRCA2, BRIP1, CDH1, CHEK2, EPCAM, FAM175A, FANCC, MLH1, MRE11A, MSH2, MSH6, MUTYH, NBN, NF1, PALB2, PMS2,*	81433	LabCorp (when performed in the states of Washington, Oregon, Idaho, Utah, California, or North Carolina)		**X**	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. MolDX has determined panels may be denied as "not medically necessary" when certain non-covered gene tests (see Table 2) are included because they do not meet Medicare's medical necessity requirements. This panel is "not medically necessary" because it includes at least	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
PTEN, RAD50, RAD51C, RAD51D, STK11 and TP53)					one of these specific excluded gene tests from Table 2 (*FANCC*). See also the following: ✓ LCD attachment for L36256, Excluded Test List – as of 08/01/2016 *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* ✓ LCD attachment for L35160, Excluded Test List – as of 08/01/2016 *(Laboratories in CA and NV)*	
VistaSeq Colorectal Cancer Profile *(APC, ATM, AXIN2, BLM, BMPR1A, BRCA1, BRCA2, CDH1, CDKN2A, CHEK2, EPCAM, MLH1, MSH2, MSH6, MUTYH, PMS2, POLD1, POLE, PTEN, SMAD4, STK11 and TP53)*	81435, 81436	LabCorp (when performed in the states of Washington, Oregon, Idaho, Utah, California, or North Carolina)	**X**		For ***CPT code 81435 for Lynch Syndrome***: ✓ Palmetto GBA LCD for MolDX: Genetic Testing for Lynch Syndrome (L35024) *(Applies to any laboratories in North Carolina) In addition to the Lynch Syndrome criteria, see also the "Definitive Molecular Testing for Lynch Syndrome" section of the LCD.* For ***CPT code 81435 for suspected Familial Adenomatous Polyposis (FAP), Attenuated FAP (AFAP) or MYH-associated polyposis (MAP):*** ✓ Palmetto GBA LCD for MolDX: APC and MUTYH Gene Testing (L36827) *(Applies to any laboratories in North Carolina)* *See also Noridian J-F LCDs L36374 and L36884, which apply to any laboratories in the health plan's service area or the Noridian J-E LCDs L36370 and*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					L36882, *which apply to any laboratories in California*	
VistaSeq Endocrine Cancer Profile *(DC73, MAX, MEN1, NF1, PRKAR1A, PTEN, RET, SDHB, SDHC, SDHD, TMEM127, TP53 and VHL)*	81437, 81438	LabCorp (when performed in the states of Washington, Oregon, Idaho, Utah, California, or North Carolina)		X	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. MolDX has determined panels may be denied as "not medically necessary" when certain non-covered gene tests (see Table 2) are included because they do not meet Medicare's medical necessity requirements. This panel is "not medically necessary" because it includes at least one of these specific excluded gene tests from Table 2. *For CPT 81438, see also* LCD attachment for L36256, Excluded Test List – as of 08/01/2016 *(For laboratories in the health plan's service area) and the* LCD attachment for L35160, Excluded Test List – as of 08/01/2016 *(For testing performed in California)*	
VistaSeq GYN Cancer Profile *(BRCA1, BRCA2, CHEK2, EPCAM, MHL1, MSH2, MSH6, MUTYH, PMS2, PTEN and TP53)*	81162, 81292, 81294, 81295, 81297, 81298, 81300, 81317, 81319, 81321, 81323, 81403, 81405, 81406, 81479	LabCorp (when performed in the states of Washington, Oregon, Idaho, Utah, California, or North Carolina)		X	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. LCDs L36082, L36161, and L36163 require all genes included in a panel be relevant to the individual being tested.	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met*		MEDICARE RATIONALE / REFERENCE	Back to Criteria
			Yes	No		
VistaSeq℠ Hereditary Cancer Panel *(APC, ATM, BARD1, BMPR1A, BRCA1, BRCA2, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, EPCAM, FAM175A, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PRKAR1A, PTEN, RAD51C, RAD51D, SMAD4, STK11, TP53)*	81162, 81201, 81203, 81292, 81294, 81295, 81297, 81298, 81300, 81317, 81319, 81321, 81323, 81403, 81404, 81405, 81406, 81408, 81479	LabCorp (when performed in the states of Washington, Oregon, Idaho, Utah, California, or North Carolina)		**X**	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. Diagnostic laboratory tests, including genetic tests, performed to determine *risk* for developing a condition are not covered under Medicare and *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...".	
***VistaSeq℠ Hereditary Cancer Panel Without* BRCA** *(APC, ATM, BARD1, BMPR1A, BRIP1, CDH1, CDK4, CDKN2A, CHEK2, EPCAM, FAM175A, MLH1, MSH2, MSH6, MUTYH, NBN, PALB2, PMS2, PRKAR1A, PTEN, RAD51C, RAD51D, SMAD4, STK11, TP53)*	81201, 81203, 81292, 81294, 81295, 81297, 81298, 81300, 81317, 81319, 81321, 81323, 81403, 81404, 81405, 81406, 81408, 81479	LabCorp (when performed in the states of Washington, Oregon, Idaho, Utah, California, or North Carolina)		**X**	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. Diagnostic laboratory tests, including genetic tests, performed to determine *risk* for developing a condition are not covered under Medicare and *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...".	
VistaSeq High/Moderate Risk Breast Cancer Profile *(ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, STK11 and TP53)*	81162, 81321, 81323, 81404, 81405, 81406, 81408, 81479	LabCorp (when performed in the states of Washington, Oregon, Idaho,		**X**	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. LCDs L36082, L36161,	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
		Utah, California, or North Carolina)			and L36163 require all genes included in a panel be relevant to the individual being tested.	
VistaSeq High Risk Colorectal Cancer Profile *(APC, EPCAM, MLH1, MSH2, MSH6, MUTYH and PMS2)*	81201, 81203, 81292, 81294, 81295, 81297, 81298, 81300, 81317, 81319, 81403, 81406	LabCorp (when performed in the states of Washington, Oregon, Idaho, Utah, California, or North Carolina)	X		For ***Lynch Syndrome***: ✓ Palmetto GBA LCD for MolDX: Genetic Testing for Lynch Syndrome (L35024) *(Applies to any laboratories in North Carolina) In addition to the Lynch Syndrome criteria, see also the "Definitive Molecular Testing for Lynch Syndrome" section of the LCD.* For ***suspected Familial Adenomatous Polyposis (FAP), Attenuated FAP (AFAP) or MYH-associated polyposis (MAP):*** ✓ Palmetto GBA LCD for MolDX: APC and MUTYH Gene Testing (L36827) *(Applies to any laboratories in North Carolina)* *See also Noridian J-F LCDs L36374 and L36884, which apply to any laboratories in the health plan's service area or the Noridian J-E LCDs L36370 and L36882, which apply to any laboratories in California*	
VistaSeq Pancreatic Cancer *(APC, ATM, BRCA1, BRCA2, CDKN2A, EPCAM, MLH1, MSH2, MSH6,*	81162, 81201, 81203, 81292, 81294, 81295, 81297, 81298, 81300, 81317,	LabCorp (when performed in the states of Washington, Oregon, Idaho,		X	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. MolDX has determined panels may be denied as "not medically necessary"	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
PALB2, PMS2, STK11, TP53 and VHL)	81319, 81403, 81404, 81405, 81406, 81408, 81479	Utah, California, or North Carolina)			when certain non-covered gene tests (see Table 2) are included because they do not meet Medicare's medical necessity requirements. This panel is "not medically necessary" because it includes at least one of these specific excluded gene tests from Table 2.	
VistaSeq Renal Cell Cancer Profile *(EPCAM, FH, FLCN, GPC3, MET, MITF (c.952G>A), MLH1, MSH2, MSH6, PTEN, PMS2, SDHB, SDHC, SDHD, TP53, TSC1, TSC2, VHL and WT1)*	81292, 81294, 81295, 81297, 81298, 81300, 81317, 81319, 81321, 81323, 81403, 81404, 81405, 81406, 81407, 81479	LabCorp (when performed in the states of Washington, Oregon, Idaho, Utah, California, or North Carolina)		X	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. MolDX has determined panels may be denied as "not medically necessary" when certain non-covered gene tests (see Table 2) are included because they do not meet Medicare's medical necessity requirements. This panel is "not medically necessary" because it includes at least one of these specific excluded gene tests from Table 2.	
Whole Exome and Whole Genome Sequencing *(including the EXaCT-1 Whole Exome and RCIGM Rapid Whole Genome Sequencing Tests)*	81415, 81416, 81417, 81425, 81426, 81427, 81479, 0036U, 0094U	Various		X	✓ LCD attachment for L36256, Excluded Test List – as of 08/01/2016 *(Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, WY)* ✓ LCD attachment for L35160, Excluded Test List – as of 08/01/2016 *(Laboratories in CA and NV)* ✓ National LCD for Molecular Pathology Procedures (L35000) *(Laboratories in IL, MN, WI, CT, NY, ME, MA, NH, RI, or VT) (This includes the EXaCT-1 Whole Exome Test, 0036U)*	

TEST NAME & GENES *If known*	CODES *If known*	PERFORMING LABORATORY & LOCATION	COVERAGE AVAILABLE? *When criteria met* Yes	No	MEDICARE RATIONALE / REFERENCE	Back to Criteria
					(Rationale: Since current codes for whole exome sequencing are non-covered, all whole exome sequencing tests are considered non-covered, regardless of what CPT code is used, until LCDs or LCAs indicate otherwise.)	
YouScript Analgesic *(CYP2D6, CYP2C9, CYP3A4, CYP3A5, CYP2B6, COMT, and OPRM1)*	81226, 81227, 81401, and/or 81479	Genelex, Seattle, WA		**X**	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. MolDX has determined panels may be denied as "not medically necessary" when certain non-covered gene tests (see Table 2) are included because they do not meet Medicare's medical necessity requirements. This panel is "not medically necessary" because it includes at least one of these specific excluded gene tests from Table 2 (CYP2B6).	
YouScript Psychotropic Plus *(CYP2D6, CYP2C19, CYP3A4, ADRA2A, CYP1A2, CYP2B6, COMT, GRIK4, HTR2A, HTR2C, MTHFR, SLC6A4/5-HTT)*	81226, 81225, 81291, 81401, and/or 81479	Genelex, Seattle, WA		**X**	Certain *single gene* tests (i.e., BRCA1/2) may be medically necessary for an individual, but many *panels* include both medically appropriate and inappropriate gene tests. MolDX has determined panels may be denied as "not medically necessary" when certain non-covered gene tests (see Table 2) are included because they do not meet Medicare's medical necessity requirements. This panel is "not medically necessary" because it includes at least one of these specific excluded gene tests from Table 2 (CYP2B6).	

**Scroll to the "All Versions" section at the bottom of the LCD or LCA to access prior versions.

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]

The MolDX program will affect diagnostic services reported with the following CPT/HCPCS codes: [13]

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

For testing performed by a laboratory outside of the Medicare Advantage Organization's (MAO) 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 mutations being tested;
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

Genetic and Molecular Diagnostics – Single Gene or Variant Testing, Genetic Testing, Policy No. M-20

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 LCA for Biomarkers for Oncology (A52986)
18. Retired Noridian LCA for Molecular Genetic testing (A52932) (Scroll to the "Public Version(s)" section at the bottom of the LCD for links to prior versions if necessary)
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: The recently added CPT® codes for molecular genetic testing are often non-specific as evidenced by the CPT range 81400-81408. Many of the tests listed for these codes are not covered by Medicare.[18] In order to properly adjudicate claims for molecular genetic testing, the actual test name being performed must be included in the narrative section of the claim.

For laboratories in the health plan's service area, instructions regarding the reporting of next generation sequencing (NGS), targeted tumor panels, or comprehensive genomic profile (CGP) testing, see the Noridian LCA for *MolDX: Next Generation Sequencing Billing and Coding Guidelines* (A55629) for coding expectations.

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

Codes	Number	Description
CPT	0004M	Scoliosis, DNA analysis of 53 single nucleotide polymorphisms (SNPs), using saliva, prognostic algorithm reported as a risk score *(ScoliScore™)*
	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)*
	~~0008M~~	~~Oncology (breast), mRNA analysis of 58 genes using hybrid capture, on formalin-fixed paraffin-embedded (FFPE) tissue, prognostic algorithm reported as a risk score *(Prosigna Breast Cancer Assay)*~~ *(Code deleted 01/01/2019)*
	0009M	Fetal aneuploidy (trisomy 21, and 18) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy *(used for the VisibiliT test)*
	0005U	Oncology (prostate) gene expression profile by real-time RT-PCR of 3 genes (ERG, PCA3, and SPDEF), urine, algorithm reported as risk score
	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
	0015U	Drug metabolism (adverse drug reactions), DNA, 22 drug metabolism and transporter genes, real-time PCR, blood or buccal swab, genotype and metabolizer status for therapeutic decision support
	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/absence of variants and associated therapy(ies) to consider
	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")

	0029U	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis (ie, CYP1A2, CYP2C19, CYP2C9, CYP2D6, CYP3A4, CYP3A5, CYP4F2, SLCO1B1, VKORC1 and rs12777823)
	0030U	Drug metabolism (warfarin drug response), targeted sequence analysis (ie, CYP2C9, CYP4F2, VKORC1, rs12777823)
	0033U	HTR2A (5-hydroxytryptamine receptor 2A), HTR2C (5-hydroxytryptamine receptor 2C) (eg, citalopram metabolism) gene analysis, common variants (ie, HTR2A rs7997012 [c.614-2211T>C], HTR2C rs3813929 [c.-759C>T] and rs1414334 [c.551-3008C>G])
	0034U	TPMT (thiopurine S-methyltransferase), NUDT15 (nudix hydroxylase 15)(eg, thiopurine metabolism), gene analysis, common variants (ie, TPMT *2, *3A, *3B, *3C, *4, *5, *6, *8, *12; NUDT15 *3, *4, *5)
	0036U	Oncology (somatic mutations). Whole Exome 22,000 genes by Next Generation Sequencing. DNA extracted and analyzed from formalin fixed paraffin embedded tissue and Whole Blood. Algorithm result type is predictive and prognostic. Report of specific gene mutations, alterations as targets for therapeutic agents.
	0037U	Broad next generation sequencing in vitro diagnostic device, solid malignant neoplasms, DNA analysis, 324 genes, detection of substitutions, insertion and deletion alterations (indels), copy number alterations (CNAs), and select gene rearrangements as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB), reported as presence/absence of variants and discrete levels of MSI and TMB, and associated therapy(ies) including multiple FDA-approved companion diagnostics, using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens.
	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
	0047U	Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score
	0048U	Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s)
	0050U	Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements
	0053U	Oncology (prostate cancer), FISH analysis of 4 genes (ASAP1, HDAC9, CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade
	0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control

	targets), plasma
0056U	Hematology (acute myelogenous leukemia), DNA, whole genome next-generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s
~~0057U~~	~~Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank~~ *(Code deleted 07/01/2019)*
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
0068U	Candida species panel (C. albicans, C. glabrata, C. parapsilosis, C. kruseii, C tropicalis, and C. auris), amplified probe technique with qualitative report of the presence or absence of each species
0078U	Pain management (opioid-use disorder) genotyping panel, 16 common variants (ie, ABCB1, COMT, DAT1, DBH, DOR, DRD1, DRD2, DRD4, GABA, GAL, HTR2A, HTTLPR, MTHFR, MUOR, OPRK1, OPRM1), buccal swab or other germline tissue sample, algorithm reported as positive or negative risk of opioid-use disorder
0081U	Oncology (uveal melanoma), mRNA, gene-expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping genes), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis
0086U	Infectious disease (bacterial and fungal), organism identification, blood culture, using rRNA FISH, 6 or more organism targets, reported as positive or negative with phenotypic minimum inhibitory concentration (MIC) -based antimicrobial susceptibility
0087U	Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes, transplant biopsy tissue, allograft rejection and injury algorithm reported as a probability score
0088U	Transplantation medicine (kidney allograft rejection) microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection
0089U	Oncology (melanoma), gene expression profiling by RTqPCR, PRAME and LINC00518, superficial collection using adhesive patch(es)
0090U	Oncology (cutaneous melanoma) mRNA gene expression profiling by RT-PCR of 23 genes (14 content and 9 housekeeping), utilizing formalin-fixed paraffin embedded tissue, algorithm reported as a categorical result (ie, benign, indeterminate, or malignant)
0091U	Oncology (colorectal) screening, cell enumeration of circulating tumor cells, utilizing whole blood, algorithm, for the presence of adenoma or cancer, reported as a positive or negative result

0092U	Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy
0094U	Genome (eg, unexplained constitutional or heritable disorder or syndrome), rapid sequence analysis
0097U	Gastrointestinal pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 22 targets (Campylobacter (C. jejuni/C. coli/C. upsaliensis), Clostridium difficile (C. difficile) toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio (V. parahaemolyticus/V. vulnificus/ V. cholerae), including specific identification of Vibrio cholerae, Yersinia enterocolitica, Enteroaggregative Escherichia coli (EAEC), Enteropathogenic Escherichia coli (EPEC), Enterotoxigenic Escherichia coli (ETEC) lt/st, Shiga-like toxin-producing Escherichia coli (STEC) stx1/stx2 (including specific identification of the E. coli O157 serogroup within STEC), Shigella/ Enteroinvasive Escherichia coli (EIEC), Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia (also known as G. intestinalis and G. duodenalis), Adenovirus F 40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, Sapovirus (Genogroups I, II, IV, and V))
0098U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 14 targets (Adenovirus, Coronavirus, Human Metapneumovirus, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype H1-2009, Influenza B, Parainfluenza Virus, Human Rhinovirus/Enterovirus, Respiratory Syncytial Virus, Bordetella pertussis, Chlamydophila pneumoniae, and Mycoplasma pneumoniae)
0099U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 20 targets (Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus, Coronavirus OC43, Human Metapneumovirus, Influenza A, Influenza A subtype, Influenza A subtype H3, Influenza A subtype H1-2009, Influenza, Parainfluenza Virus, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Human Rhinovirus/Enterovirus, Respiratory Syncytial Virus, Bordetella pertussis, Chlamydophila pneumonia, Mycoplasma pneumoniae)
0100U	Respiratory pathogen, multiplex reverse transcription and multiplex amplified probe technique, multiple types or subtypes, 21 targets (Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, including subtypes H1, H1-2009, and H3, Influenza B, Parainfluenza Virus 1, Parainfluenza Virus 2, Parainfluenza Virus 3, Parainfluenza Virus 4, Respiratory Syncytial Virus, Bordetella parapertussis (IS1001), Bordetella pertussis (ptxP), Chlamydia pneumoniae, Mycoplasma pneumoniae)
0101U	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic

	sequence analysis panel utilizing a combination of NGS, Sanger, MLPA and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated [15 genes (sequencing and deletion/duplication), EPCAM and GREM1 (deletion/duplication only)]
0102U	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated [17 genes (sequencing and deletion/duplication)]
0103U	Hereditary ovarian cancer (eg, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated [24 genes (sequencing and deletion/duplication); EPCAM (deletion/duplication only)]
~~0104U~~	~~Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer); genomic sequence analysis panel utilizing a combination of NGS, Sanger, MLPA and array CGH, with MRNA analytics to resolve variants of unknown significance when indicated [32 genes (sequencing and deletion/duplication); EPCAM and GREM1 (deletion/duplication only)]~~ *(Code deleted 10/01/2019)*
0105U	Nephrology (chronic kidney disease), multiplex electrochemiluminescent immunoassay (ECLIA) of tumor necrosis factor receptor 1A, receptor superfamily 2 (TNFR1, TNFR2), and kidney injury molecule-1 (KIM-1) combined with longitudinal clinical data, including APOL1 genotype if available, and plasma (isolated fresh or frozen), algorithm reported as probability score for rapid kidney function decline (RKFD)
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 paraffinembedded tissue, algorithm reported as risk of progression to high-grade dysplasia or cancer
0109U	Infectious disease (Aspergillus species), real-time PCR for detection of DNA from 4 species (A. fumigatus, A. terreus, A. niger, and A. flavus), blood, lavage fluid, or tissue, qualitative reporting of presence or absence of each species
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
0112U	Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug resistance gene
0113U	Oncology (prostate), measurement of PCA3 and TMPRSS2-ERG in urine and PSA in serum following prostatic massage, by RNA amplification and fluorescencebased detection, algorithm reported as risk score

	0115U	Respiratory infectious agent detection by nucleic acid (DNA and RNA), 18 viral types and subtypes and 2 bacterial targets, amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
	0118U	Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA
	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
	0126U	Fetal congenital abnormalities and perinatal complications, biochemical assays of 5 analytes (free beta-hCG, PAPP-A, AFP, placental growth factor, and inhibin-A), time-resolved fluorescence immunoassay, includes qualitative assessment of Y chromosome in cell-free fetal DNA, maternal serum and plasma, predictive algorithm reported as a risk scores for fetal trisomies 13/18, 21, and preeclampsia
	0128U	Obstetrics (preeclampsia), biochemical assays of 3 analytes (PAPP-A, AFP, and placental growth factor), time-resolved fluorescence immunoassay, includes qualitative assessment of Y chromosome in cell-free fetal DNA, maternal serum and plasma, predictive algorithm reported as a risk score for preeclampsia
	0129U	Hereditary breast cancer–related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), genomic sequence analysis and deletion/duplication analysis panel (ATM, BRCA1, BRCA2, CDH1, CHEK2, PALB2, PTEN, and TP53)
	0130U	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis), targeted mRNA sequence analysis panel (APC, CDH1, CHEK2, MLH1, MSH2, MSH6, MUTYH, PMS2, PTEN, and TP53) (List separately in addition to code for primary procedure) (Use 0130U in conjunction with 81435, 0101U)
	0131U	Hereditary breast cancer–related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (13 genes) (List separately in addition to code for primary procedure) (Use 0131U in conjunction with 81162, 81432, 0102U)
	0132U	Hereditary ovarian cancer–related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer), targeted mRNA sequence analysis panel (17 genes) (List separately in addition to code for primary procedure) (Use 0132U in conjunction with 81162, 81432, 0103U)
	0133U	Hereditary prostate cancer–related disorders, targeted mRNA sequence analysis panel (11 genes) (List separately in addition to code for primary procedure) (Use 0133U in conjunction with 81162)

	0134U	Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (18 genes) (List separately in addition to code for primary procedure) (Use 0134U in conjunction with 81162, 81432, 81435)
	0135U	Hereditary gynecological cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), targeted mRNA sequence analysis panel (12 genes) (List separately in addition to code for primary procedure) (Use 0135U in conjunction with 81162)
	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)
	81105	Human platelet antigen 1 genotyping (HPA-1), ITGB3 (integrin, beta 3 [platelet glycoprotein iiia], antigen CD61 [GPIIIA]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-1A/B (L33P)
	81106	Human platelet antigen 2 genotyping (HPA-2), GP1BA (glycoprotein ib [platelet], alpha polypeptide [GPIBA]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-2A/B (T145M)
	81107	Human platelet antigen 3 genotyping (HPA-3), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIB of IIB/IIIA complex], antigen CD41 [GPIIB]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-3A/B (I843S)
	81108	Human platelet antigen 4 genotyping (HPA-4), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIA], antigen CD61 [GPIIIA]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-4A/B (R143Q)
	81109	Human platelet antigen 5 genotyping (HPA-5), ITGA2 (integrin, alpha 2 [CD49B, alpha 2 subunit of VLA-2 receptor] [GPIA]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant (eg, HPA-5A/B (K505E))
	81110	Human platelet antigen 6 genotyping (HPA-6W), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIA, antigen CD61] [GPIIIA]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-6A/B (R489Q)
	81111	Human platelet antigen 9 genotyping (HPA-9W), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIB of IIB/IIIA complex, antigen CD41] [GPIIB]) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-9A/B (V837M)
	81112	Human platelet antigen 15 genotyping (HPA-15), CD109 (CD109 molecule) (eg, neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-15A/B (S682Y)
	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)
	81161	*DMD (dystrophin)* (e.g., Duchenne/Becker muscular dystrophy) deletion analysis and duplication analysis, if performed
	81162	*BRCA1 (BRCA1, DMA repair associated), BRCA2 (BRCA2, DNA repair associated)* (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and full duplication/deletion analysis (ie, detection of large gene rearrangements)
	81163	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
	81164	BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
	81165	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
	81166	BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
	81167	BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
	81170	*ABL1 (ABL proto-oncogene 1, non-receptor tyrosine kinase)* (eg, acquired imatinib tyrosine kinase inhibitor resistance), gene analysis, variants in the kinase domain
	81171	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
	81172	AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; characterization of alleles (eg, expanded size and methylation status)
	81173	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; full gene sequence
	81174	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; known familial variant
	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)
	81177	ATN1 (atrophin 1) (eg, dentatorubral-pallidoluysian atrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
	81178	ATXN1 (ataxin 1) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
	81179	ATXN2 (ataxin 2) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

81180	ATXN3 (ataxin 3) (eg, spinocerebellar ataxia, Machado-Joseph disease) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81181	ATXN7 (ataxin 7) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81182	ATXN8OS (ATXN8 opposite strand [non-protein coding]) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81183	ATXN10 (ataxin 10) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81184	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
81185	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; full gene sequence
81186	CACNA1A (calcium voltage-gated channel subunit alpha1 A) (eg, spinocerebellar ataxia) gene analysis; known familial variant
81187	CNBP (CCHC-type zinc finger nucleic acid binding protein) (eg, myotonic dystrophy type 2) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
81188	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
81189	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; full gene sequence
81190	CSTB (cystatin B) (eg, Unverricht-Lundborg disease) gene analysis; known familial variant(s)
81200	*ASPA (aspartoacylase)* (eg, Canavan disease) gene analysis, common variants (eg, E285A, Y231X)
81201	*APC (adenomatous polyposis coli)* (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence
81202	; known familial variants
81203	; duplication/deletion variants
81204	AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, Kennedy disease, X chromosome inactivation) gene analysis; characterization of alleles (eg, expanded size or methylation status)
81205	*BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide)* (eg, maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X)
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
81209	*BLM (Bloom syndrome, RecQ helicase-like)* (eg, Bloom syndrome) gene analysis, 2281del6ins7 variant
81210	*BRAF (B-Raf proto-oncogene, serine/threonine kinase)* (eg, colon cancer, melanoma), gene analysis, V600E variant(s)

~~81211~~	~~*BRCA1, BRCA2 (breast cancer 1 and 2)* (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants in BRCA1 (ie, exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)~~ *(Code deleted 01/01/2019)*
81212	*BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, DNA repair associated)* (eg, hereditary breast and ovarian cancer) gene analysis; 185delAG, 5385insC, 6174delT variants
~~81213~~	~~; uncommon duplication/deletion variants~~ *(Code deleted 01/01/2019)*
~~81214~~	~~*BRCA1 (breast cancer 1)* (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis and common duplication/deletion variants (ie, exon 13 del 3.835kb, exon 13 dup 6kb, exon 14-20 del 26kb, exon 22 del 510bp, exon 8-9 del 7.1kb)~~ *(Code deleted 01/01/2019)*
81215	*BRCA1 (BRCA1, DNA repair associated)* (eg, hereditary breast and ovarian cancer) gene analysis; known familial variant
81216	*BRCA2 (BRCA2, DNA repair associated)* (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
81217	; known familial variant
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
81220	*CFTR (cystic fibrosis transmembrane conductance regulator)* (eg, cystic fibrosis) gene analysis; common variants (eg, ACMG/ACOG guidelines)
81221	; known familial variants
81222	; duplication/deletion variants
81223	; full gene sequence
81224	; intron 8 poly-T analysis (eg, male infertility)
81225	*CYP2C19 (cytochrome P450, family 2, subfamily C, polypeptide 19)* (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *8, *17)
81226	*CYP2D6 (cytochrome P450, family 2, subfamily D, polypeptide 6)* (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *9, *10, *17, *19, *29, *35, *41, *1XN, *2XN, *4XN)
81227	*CYP2C9 (cytochrome P450, family 2, subfamily C, polypeptide 9)* (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *5, *6)
81228	Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (eg, bacterial artificial chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)
81229	; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants for chromosomal abnormalities
81230	CYP3A4 (cytochrome P450 family 3 subfamily A member 4) (eg, drug metabolism), gene analysis, common variant(s) (eg, *2, *22)
81231	*CYP3A5* (cytochrome P450 family 3 subfamily A member 5) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3, *4, *5, *6, *7)

81233	*BTK* (Bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)
81234	*DMPK* (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; evaluation to detect abnormal (expanded) alleles
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)
81238	*F9* (coagulation factor IX) (eg, hemophilia B), full gene sequence
81239	*DMPK* (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; characterization of alleles (eg, expanded size)
81240	*F2 (prothrombin, coagulation factor II)* (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant
81241	*F5 (coagulation factor V)* (eg, hereditary hypercoagulability) gene analysis, Leiden variant
81242	*FANCC (Fanconi anemia, complementation group C)* (eg, Fanconi anemia, type C) gene analysis, common variant (eg, IVS4+4A>T)
81243	*FMR1 (fragile X mental retardation 1)* (eg, fragile X mental retardation) gene analysis; characterization of alleles (expanded size and promoter methylation status)
81244	; characterization of alleles (eg, expanded size and methylation status)
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)
81247	*G6PD* (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; common variant(s) (eg, a, a-)
81248	; known familial variant(s)
81249	; full gene sequence
81250	*G6PC (glucose-6-phosphatase, catalytic subunit)* (eg, Glycogen storage disease, type 1a, von Gierke disease) gene analysis, common variants (eg, R83C, Q347X)
81251	*GBA (glucosidase, beta, acid)* (eg, Gaucher disease) gene analysis, common variants (eg, N370S, 84GG, L444P, IVS2+1G>A)
81252	*GJB2 (gap junction protein, beta 2, 26kDa, connexin 26)* (eg, nonsyndromic hearing loss) gene analysis; full gene sequence
81253	; known familial variants
81254	*GJB6 (gap junction protein, beta 6, 30kDa, connexin 30)* (eg, nonsyndromic hearing loss) gene analysis, common variants (eg, 309kb [del(GJB6-D13S1830)] and 232kb [del(GJB6-D13S1854)])
81255	*HEXA (hexosaminidase A [alpha polypeptide])* (eg, Tay-Sachs disease) gene analysis, common variants (eg, 1278insTATC, 1421+1G>C, G269S)

	81256	*HFE (hemochromatosis)* (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D)
	81257	*HBA1/HBA2 (alpha globin 1 and alpha globin 2)* (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis, for common deletions or variant (eg, Southeast Asian, Thai, Filipino, Mediterranean, alpha3.7, alpha4.2, alpha20.5, and Constant Spring)
	81258	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; known familial variant
	81259	; full gene sequence
	81260	*IKBKAP (inhibitor of kappa light polypeptide gene enhancer in B-cells, kinase complex-associated protein)* (eg, familial dysautonomia) gene analysis, common variants (eg, 2507+6T>C, R696P)
	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)
	81265	Comparative analysis using Short Tandem Repeat (STR) markers; patient and comparative specimen (eg, pre-transplant recipient and donor germline testing, post-transplant non-hematopoietic recipient germline [eg, buccal swab or other germline tissue sample] and donor testing, twin zygosity testing, or maternal cell contamination of fetal cells)
	81266	; each additional specimen (eg, additional cord blood donor, additional fetal samples from different cultures, or additional zygosity in multiple birth pregnancies) (List separately in addition to code for primary procedure)
	81267	Chimerism (engraftment) analysis, post transplantation specimen (eg, hematopoietic stem cell), includes comparison to previously performed baseline analyses; without cell selection
	81268	; with cell selection (eg, CD3, CD33), each cell type
	81269	HBA1/HBA2 (alpha globin 1 and alpha globin 2) (eg, alpha thalassemia, Hb Bart hydrops fetalis syndrome, HbH disease), gene analysis; duplication/deletion variants
	81270	*JAK2 (Janus kinase 2)* (eg, myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant
	81271	HTT (huntingtin) (eg, Huntington disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
	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)
	81274	HTT (huntingtin) (eg, Huntington disease) gene analysis; characterization of alleles (eg, expanded size)
	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)
	81283	IFNL3 (interferon, lambda 3) (eg, drug response), gene analysis, rs12979860 variant
	81284	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; evaluation to detect abnormal (expanded) alleles
	81285	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; characterization of alleles (eg, expanded size)
	81286	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; full gene sequence
	81287	*MGMT (O-6-methylguanine-DNA methyltransferase)* (eg, glioblastoma multiforme) promoter methylation analysis
	81288	MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; promoter methylation analysis
	81289	FXN (frataxin) (eg, Friedreich ataxia) gene analysis; known familial variant(s)
	81290	*MCOLN1 (mucolipin 1)* (eg, Mucolipidosis, type IV) gene analysis, common variants (eg, IVS3-2A>G, del6.4kb)
	81291	*MTHFR (5,10-methylenetetrahydrofolate reductase)* (eg, hereditary hypercoagulability) gene analysis, common variants (eg, 677T, 1298C)
	81292	*MLH1 (mutL homolog 1, colon cancer, nonpolyposis type 2)* (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
	81293	; known familial variants
	81294	; duplication/deletion variants
	81295	*MSH2 (mutS homolog 2, colon cancer, nonpolyposis type 1)* (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
	81296	; known familial variants
	81297	; duplication/deletion variants
	81298	*MSH6 (mutS homolog 6 [E. coli])* (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
	81299	; known familial variants
	81300	; duplication/deletion variants
	81301	Microsatellite instability analysis (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (eg, BAT25, BAT26), includes comparison of neoplastic and normal tissue, if performed
	81302	*MECP2 (methyl CpG binding protein 2)* (eg, Rett syndrome) gene analysis; full sequence analysis
	81303	; known familial variant

81304	; duplication/deletion variants
81305	MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant
81306	NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *3, *4, *5, *6)
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)
81312	PABPN1 (poly[A] binding protein nuclear 1) (eg, oculopharyngeal muscular dystrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
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
81317	*PMS2 (postmeiotic segregation increased 2 [S. cerevisiae])* (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis
81318	; known familial variants
81319	; duplication/deletion variants
81320	PLCG2 (phospholipase C gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)
81321	*PTEN (phosphatase and tensin homolog)* (eg, Cowden syndrome, *PTEN* hamartoma tumor syndrome) gene analysis; full sequence analysis
81322	; known familial variant
81323	; duplication/deletion variant
81324	*PMP22 (peripheral myelin protein 22)* (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; duplication/deletion analysis
81325	; full sequence analysis
81326	; known familial variant
81327	SEPT9 (Septin9) (eg, colorectal cancer) promoter methylation analysis
81328	SLCO1B1 (solute carrier organic anion transporter family, member 1B1) (eg, adverse drug reaction), gene analysis, common variant(s) (eg, *5)
81329	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed

	81330	*SMPD1(sphingomyelin phosphodiesterase 1, acid lysosomal)* (eg, Niemann-Pick disease, Type A) gene analysis, common variants (eg, R496L, L302P, fsP330)
	81331	*SNRPN/UBE3A (small nuclear ribonucleoprotein polypeptide N and ubiquitin protein ligase E3A)* (eg, Prader-Willi syndrome and/or Angelman syndrome), methylation analysis
	81332	*SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1)* (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, *S and *Z)
	81333	TGFBI (transforming growth factor beta-induced) (eg, corneal dystrophy) gene analysis, common variants (eg, R124H, R124C, R124L, R555W, R555Q)
	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)
	81335	TPMT (thiopurine S-methyltransferase) (eg, drug metabolism), gene analysis, common variants (eg, *2, *3)
	81336	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence
	81337	SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)
	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)
	81343	PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
	81344	TBP (TATA box binding protein) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
	81345	TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)
	81350	*UGT1A1 (UDP glucuronosyltransferase 1 family, polypeptide A1)* (eg, irinotecan metabolism), gene analysis, common variants (eg, *28, *36, *37)
	81355	*VKORC1 (vitamin K epoxide reductase complex, subunit 1)* (eg, warfarin metabolism), gene analysis, common variant(s) (eg, -1639G>A, c. 173+1000C>T)
	81361	HBB (hemoglobin, subunit beta) (eg, sickle cell anemia, beta thalassemia, hemoglobinopathy); common variant(s) (eg, HBS, HBC, HBE)
	81362	; known familial variant(s)
	81363	; duplication/deletion variant(s)
	81364	; full gene sequence

81370	*HLA Class I and II typing, low resolution* (eg, antigen equivalents); *HLA-A, -B, -C, -DRB1/3/4/5, and -DQB1*
81371	; *HLA-A, -B, and -DRB1* (eg, verification typing)
81372	*HLA Class I typing, low resolution* (eg, antigen equivalents); complete (ie, *HLA-A, -B, and -C*)
81373	; one locus (eg, HLA-A, -B, or -C), each
81374	; one antigen equivalent (eg, B*27), each
81375	*HLA Class II typing, low resolution* (eg, antigen equivalents); *HLA-DRB1/3/4/5 and -DQB1*
81376	; one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each
81377	; one antigen equivalent, each
81378	*HLA Class I and II typing, high resolution* (ie, alleles or allele groups), *HLA-A, -B, -C, and -DRB1*
81379	*HLA Class I typing, high resolution* (ie, alleles or allele groups); complete (ie, HLA-A, -B, and -C)
81380	; one locus (eg, HLA-A, -B, or -C), each
81381	; one allele or allele group (eg, B*57:01P), each
81382	*HLA Class II typing, high resolution* (ie, alleles or allele groups); one locus (eg, HLA-DRB1, -DRB3/4/5, -DQB1, -DQA1, -DPB1, or -DPA1), each
81383	; one allele or allele group (eg, HLA-DQB1*06:02P), each
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
81410	Aortic dysfunction or dilation (eg, Marfan syndrome, Loeys Dietz syndrome, Ehler Danlos syndrome type IV, arterial tortuosity syndrome); genomic sequence analysis panel, must include sequencing of at least 9 genes, including FBN1, TGFBR1, TGFBR2, COL3A1, MYH11, ACTA2, SLC2A10, SMAD3, and MYLK
81411	; duplication/deletion analysis panel, must include analyses for TGFBR1, TGFBR2, MYH11, and COL3A1
81412	Ashkenazi Jewish associated disorders (eg, Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay-Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1
81413	Cardiac ion channelopathies (eg, Brugada syndrome, long QT syndrome, short QT syndrome, catecholaminergic polymorphic ventricular tachycardia); genomic sequence analysis panel, must include sequencing

	of at least 10 genes, including ANK2, CASQ2, CAV3, KCNE1, KCNE2, KCNH2, KCNJ2, KCNQ1, RYR2, and SCN5A
81414	; duplication/deletion gene analysis panel, must include analysis of at least 2 genes, including KCNH2 and KCNQ1
81415	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis
81416	; sequence analysis, each comparator exome (eg, parents, siblings) (List separately in addition to code for primary procedure)
81417	; re-evaluation of previously obtained exome sequence (eg, updated knowledge or unrelated condition/syndrome)
81420	Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21
81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (eg, DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood
81425	Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis
81426	; sequence analysis, each comparator genome (eg, parents, siblings) (List separately in addition to code for primary procedure)
81427	; re-evaluation of previously obtained genome sequence (eg, updated knowledge or unrelated condition/syndrome)
81430	Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel, must include sequencing of at least 60 genes, including *CDH23, CLRN1, GJB2, GPR98, MTRNR1, MYO7A, MYO15A, PCDH15, OTOF, SLC26A4, TMC1, TMPRSS3, USH1C, USH1G, USH2A*, and *WFS1*
81431	; duplication/deletion analysis panel, must include copy number analyses for STRC and DFNB1 deletions in GJB2 and GJB6 genes
81432	Hereditary breast cancer-related disorders (eg, hereditary breast cancer, hereditary ovarian cancer, hereditary endometrial cancer); genomic sequence analysis panel, must include sequencing of at least 10 genes, including ATM, BRCA1, BRCA2, BRIP1, CDH1, MLH1, MSH2, MSH6, NBN, PALB2, PTEN, RAD51C, STK11, and TP53
81433	; duplication/deletion analysis panel, must include analyses for BRCA1, BRCA2, MLH1, MSH2, and STK11
81434	Hereditary retinal disorders (eg, retinitis pigmentosa, Leber congenital amaurosis, cone-rod dystrophy), genomic sequence analysis panel, must include sequencing of at least 15 genes, including ABCA4, CNGA1, CRB1, EYS, PDE6A, PDE6B, PRPF31, PRPH2, RDH12, RHO, RP1, RP2, RPE65, RPGR, and USH2A
81435	Hereditary colon cancer disorders (eg, Lynch syndrome, PTEN hamartoma syndrome, Cowden syndrome, familial adenomatosis polyposis); genomic sequence analysis panel, must include analysis of at least 10 genes, including *APC, BMPR1A, CDH1, MLH1, MSH2, MSH6, MUTYH, PTEN, SMAD4, and STK11*

81436	; duplication/deletion of gene analysis panel, must include analysis of at least 5 genes, including *MLH1, MSH2, EPCAM, SMAD4, and STK11*
81437	Hereditary neuroendocrine tumor disorders (eg, medullary thyroid carcinoma, parathyroid carcinoma, malignant pheochromocytoma or paraganglioma); genomic sequence analysis panel, must include sequencing of at least 6 genes, including MAX, SDHB, SDHC, SDHD, TMEM127, and VHL
81438	; duplication/deletion analysis panel, must include analyses for SDHB, SDHC, SDHD, and VHL
81439	Inherited cardiomyopathy (eg, hypertrophic cardiomyopathy, dilated cardiomyopathy, arrhythmogenic right ventricular cardiomyopathy) genomic sequence analysis panel, must include sequencing of at least 5 cardiomyopathy-related genes, including DSG2, MYBPC3, MYH7, PKP2, and TTN
81440	Nuclear encoded mitochondrial genes (eg, neurologic or myopathic phenotypes), genomic sequence panel, must include analysis of at least 100 genes, including BCS1L, C10orf2, COQ2, COX10, DGUOK, MPV17, OPA1, PDSS2, POLG, POLG2, RRM2B, SCO1, SCO2, SLC25A4, SUCLA2, SUCLG1, TAZ, TK2, and TYMP
81442	Noonan spectrum disorders (eg, Noonan syndrome, cardio-facio-cutaneous syndrome, Costello syndrome, LEOPARD syndrome, Noonan-like syndrome), genomic sequence analysis panel, must include sequencing of at least 12 genes, including BRAF, CBL, HRAS, KRAS, MAP2K1, MAP2K2, NRAS, PTPN11, RAF1, RIT1, SHOC2, and SOS1
81443	Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)
81445	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
81448	Hereditary peripheral neuropathies (eg, Charcot-Marie-Tooth, spastic paraplegia), genomic sequence analysis panel, must include sequencing of at least 5 peripheral neuropathy-related genes (eg, BSCL2, GJB1, MFN2, MPZ, REEP1, SPAST, SPG11, SPTLC1)
81450	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA analysis and RNA analysis when performed, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants,

	and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed
81455	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis and RNA analysis when performed, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
81460	Whole mitochondrial genome (eg, Leigh syndrome, mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes [MELAS], myoclonic epilepsy with ragged-red fibers [MERFF], neuropathy, ataxia, and retinitis pigmentosa [NARP], Leber hereditary optic neuropathy [LHON]), genomic sequence, must include sequence analysis of entire mitochondrial genome with heteroplasmy detection
81465	Whole mitochondrial genome large deletion analysis panel (eg, Kearns-Sayre syndrome, chronic progressive external ophthalmoplegia), including heteroplasmy detection, if performed
81470	X-linked intellectual disability (XLID) (eg, syndromic and non-syndromic XLID); genomic sequence analysis panel, must include sequencing of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2
81471	; duplication/deletion gene analysis, must include analysis of at least 60 genes, including ARX, ATRX, CDKL5, FGD1, FMR1, HUWE1, IL1RAPL, KDM5C, L1CAM, MECP2, MED12, MID1, OCRL, RPS6KA3, and SLC16A2
81479	Unlisted molecular pathology procedure
81493	Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, algorithm reported as a risk score
81504	Oncology (tissue of origin), microarray gene expression profiling of > 2000 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as tissue similarity scores
81507	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy
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
	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
	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
	81545	Oncology (thyroid), gene expression analysis of 142 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
	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	S3854	Gene expression profiling panel for use in the management of breast cancer treatment *(Not valid for Medicare purposes)*

Note: HCPCS code S3854 is not valid for use for Medicare Advantage members. CPT code 81519 should be used instead.

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