Genetic Testing

Policy Number: MCS040.05
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Instructions for Use

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Coverage Guidelines

Genetic testing and counseling are covered when Medicare coverage criteria are met.

Note: Screening services, such as predictive and pre-symptomatic genetic tests and services, are those used to detect an undiagnosed disease or disease predisposition, and as such are not a Medicare benefit and not covered by Medicare. However, Medicare does cover a broad range of legislatively mandated preventive services to prevent disease, detect disease early when it is most treatable and curable, and manage disease so that complications can be avoided. These services can be found on the CMS website at http://www.cms.hhs.gov/prevntiongeninfo/01_overview.asp. (Accessed January 28, 2022)

Tumor Markers

Tumor markers are covered when criteria are met; refer to the following NCDs:

- Tumor Antigen by Immunoassay – CA 125 (190.28)
- Tumor Antigen by Immunoassay – CA 19-9 (190.30)
- Tumor Antigen by Immunoassay – CA 15-3/CA 27.29 (190.29)
- Carcinoembryonic Antigen (190.26)
- Prostate Specific Antigen (190.31)
- Alpha-fetoprotein (190.25)

(Accessed January 28, 2022)

Cytogenetic Studies

Cytogenetic studies are used to describe the microscopic examination of the physical appearance of human chromosomes. Cytogenetic studies are covered when reasonable and necessary for the diagnosis or treatment of the following conditions:

- Genetic disorders (e.g., mongolism) in a fetus;
- Failure of sexual development;
- Chronic myelogenous leukemia;
- Acute leukemias lymphoid (FAB L1-L3), myeloid (FAB M0-M7), and unclassified; or
- Myodysplasia

Refer to the National Coverage Determination (NCD) for Cytogenetic Studies (190.3). (Accessed January 28, 2022)

Molecular Diagnostic Genetic Tests Included in the Palmetto MolDX Program

Refer to the Molecular Diagnostic Genetic Tests included in the Palmetto MolDX Program table for specific LCDs/LCAs and applicable coverage guidelines.

Note: The Molecular Diagnostic Genetic Tests included in the Palmetto MolDX Program table is a list, but not all-inclusive, of tests that have completed the MolDX Technical Assessment Process. For the most current MolDX information go to MolDX Coding and Billing Guidelines.

Other Molecular Diagnostic Genetic Tests

MyPRS™ Test for Multiple Myeloma Gene Expression Profile (CPT code 81479)

Medicare does not have a National Coverage Determination (NCD) for MyPRS™ test for multiple myeloma gene expression profile. Local Coverage Determinations (LCDs)/Local Coverage Article (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for MyPRS™ Test for Multiple Myeloma Gene Expression Profile.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions.

Note: After checking the MyPRS™ Test for Multiple Myeloma Gene Expression Profile table and searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

PancraGEN® (Powered by Pathfinder TG) (CPT code 81479)

Medicare does not have a National Coverage Determination (NCD) for PancraGEN®. Only one contractor has Local Coverage Determinations (LCDs) which address, i.e., Novitas Solutions, Inc., for the following states: AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, and TX. Compliance with these LCDs is required where applicable. Refer to the LCD for Loss-of-Heterozygosity Based Topographic Genotyping with PathfinderTG® (L34864). This test is provided to Medicare beneficiaries throughout the United States by Interpace Diagnostics in Pittsburgh, PA.

For coverage and payment information for all states/territories, refer to the LCD for Loss-of-Heterozygosity Based Topographic Genotyping with PathfinderTG® (L34864).

Notes:

- After searching the Medicare Coverage Database, if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.
- For additional Medicare guidance, refer to the Medicare Managed Care Manual Chapter 4, §90.4.1 – MAC with Exclusive Jurisdiction over a Medicare Item or Service.

(Accessed January 28, 2022)

Next Generation Sequencing (NGS)

For coverage guidelines, refer to the NCD for Next Generation Sequencing (NGS) (90.2).

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these LCDs/LCAs is required where applicable. These policies are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.

NGS Test Description

Clinical laboratory diagnostic tests can include tests that, for example, predict the risk associated with one or more genetic variations. In addition, in vitro companion diagnostic laboratory tests provide a report of test results of genetic variations and are essential for the safe and effective use of a corresponding therapeutic product. Next Generation Sequencing (NGS) is one technique that can measure one or more genetic variations as a laboratory diagnostic test, such as when used as a companion in vitro diagnostic test.

NGS is not a specific test but a sequencing methodology utilized to capture genomic information. Unlike Sanger sequencing (the prior standard technology) that typically provides sequence information for a single DNA strand/molecule, NGS allows for massively parallel sequencing of millions of DNA molecules concurrently [9, 10]. This allows for capturing many relevant genomic targets simultaneously, usually by utilizing capture technologies such as by PCR amplification or hybrid capture. As such, NGS tests for use in cancer are often comprised of gene panels whose content is either relevant to a specific tumor type or condition, or a larger panel of genes that can be used for multiple tumor types, including in hematopoietic malignancies.

NGS tests can vary significantly for many reasons. While NGS defines a broad methodology for massively parallel sequencing, different technologies that have different strengths, weaknesses, and technical limitations or liabilities are available [11]. The most common sequencing platforms in clinical use today are from Illumina and Thermo Fisher. While both sequence by synthesis similar to Sanger sequencing, these platforms utilize different chemistries, signal amplification, and detection methods. Gene panels can include only the portions of genes that contain the most critical clinically relevant information, or be comprehensive, containing entire exonic gene regions (coding regions), introns (non-coding regions), and even sequence RNA for detecting gene fusions. Downstream from the pre-analytic processes mentioned above, the bioinformatics used to process and assess the resultant sequencing reads and identify variants/mutations can yield different results based on the software used and what variant types of variants the test is attempting to detect. These software tools must take the resultant sequencing file (generally starting with the FASTQ format), align all possible sequences with a reference genome (BAM/SAM), and identify variants from the reference (typically a VCF file) [6]. Once such variants are identified, they must be assessed for validity and subsequently for their clinical relevance. The types of genomic information reported can vary, as tests can uncover a myriad of genomic alterations such as single nucleotide variants (SNVs), Insertions/Deletions (INDELs), Copy Number Alterations (CNAs; these can be simply amplifications at a single locus or chromosomal gains and losses), and gene fusions/translocations. The resultant information can also be used to calculate additional relevant information, such as Tumor Mutation Burden (TMB), or the presence of microsatellite instability (MSI). All of these variant classes have demonstrated clinical utility. As such, NGS testing in cancer comprises a large heterogeneous group of assays that are substantially different from each other. Additionally, NGS testing is highly complex and requires expertise from handling the specimen, to running complex equipment, to understanding the required bioinformatics, to interpreting the findings and creating an actionable medical report.

Two types of tests are considered for coverage, “Hot-spot” tests and comprehensive genomic profile tests (CGP). The definition of these terms, in addition to appropriate coding information is located in Billing and Coding Articles associated with this LCD. These tests can detect any combination of the previously described variant types, but in general, Hot-spot tests are limited to SNVs and small INDELs, whereas CGPs can detect those variants in addition to CNAs, larger INDELs, gene fusions/translocations, and be used to calculate MSI status and TMB when relevant.
Refer to the MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies (L38176).
(Accessed January 28, 2022)

Pharmacogenomic Testing for Warfarin Response (CYP2C9 and VKORC1) (CPT codes 81227 and 81355)

Effective August 3, 2009, the Centers for Medicare & Medicaid Services (CMS) believes that the available evidence supports that coverage with evidence development (CED) under §1862(a)(1)(E) of the Social Security Act (the Act) is appropriate for pharmacogenomic testing of CYP2C9 or VKORC1 alleles to predict warfarin responsiveness by any method, and is therefore covered only when provided to Medicare beneficiaries who are candidates for anticoagulation therapy with warfarin who meet the criteria outlined in the NCD for Pharmacogenomic Testing for Warfarin (90.1).

The list of Medicare approved clinical trials is available at http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Pharmacogenomic-Testing-for-Warfarin-Response.html.

For payment rules for NCDs requiring CED, refer to the Coverage Summary titled Experimental Procedures and Items, Investigational Devices and Clinical Trials.

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these LCDs/LCAs is required where applicable. These policies are available at https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.
(Accessed January 28, 2022)

Note: For a list of applicable LCDs/LCAs see Pharmacogenomics Testing in the table below.

Supporting Information

Molecular Diagnostic Genetic Tests Included in the Palmetto MolDX Program
Accessed January 28, 2022
*Also refer to the MACs with corresponding States/Territories.
Note: Only use the WPS LCD/LCA if no other Part A LCD/LCA.
For states/territories with no LCDs/LCAs, refer to the applicable Palmetto MolDX Program Guideline for coverage guidelines.

Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
4Kscore® Assay	81539	L36763 (A56932)	L37120 (A57336) L37122 (A57337)	L36979 (A56944)	L37013 (A57556)	L37792 (A56653)		L37798 (A56287)
4q25-AF Risk Genotype Coding	81479	A53457	A55091 A55090	L36021 (A54241)	L36807 (A55137)			
9p21 Genotype Test	81479	A53657	A55093 A55092	L36021 (A54242)	L36807 (A55138)			
Abbott RealTime IDH1 and IDH2 testing for Acute Myeloid Leukemia (AML)	81120 81121	L35025 (A55695)	L35160 (A55711) L36256 (A55712)	L36021 (A55716)	L36807 (A55738)	L35396 (A52986)	L35000 (A56199)	L34519 (A57451)
Afirma™ Assay by Veracyte	81546	L35025 (A53098)	L35160 (A54356) L36256 (A54358)	L36021 (A54185)	L36807 (A55138)	L35396 (A52986)	L35000 (A56199)	
APC and MUTYH Gene Testing	81201 81202 81203 81401 81403 81406 81435 81436 81479 0157U	L36827 (A56824)	L36882 (A57352) L36884 (A57353)	L36910 (A56828)	L37224 (A56901)	L35062 (A56541)	L35000 (A56199)	

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Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
AlloMap	81595	L35025 (A53099)	L35160 (A54364) L36256 (A54366)	L36021 (A54186)	L36807 (A55140)	L35396 (A52986)	L35000 (A56199)	L34519 (A57451)
ApoE Genotype	81401	A53652	L36358 (A55094) L36362 (A55095)	L36021 (A54244)	L36807 (A55141)	L35396 (A52986)	L35000 (A56199)	L34519 (A57451)
Arrhythmogenic Right Ventricular Dysplasia/ Cardiomyopathy (ARVD/C) Testing	81439	L36129 (A53605)	L36358 (A54975) L36362 (A54976)	L36021 (A54685)	L36807 (A55235)			
Aspartoacylase 2 Deficiency (ASPA) Testing	81200 81412 81443 81479	A53602	A55089 A55088	L36021 (A54253)	L36807 (A55142)			
ATP7B Gene Tests	81406 81443 81479	A53550	A55097 A55098	L36021 (A54254)	L36807 (A55143)			
Avise PG	84999	L35025 (A53100)	L35160 (A54376) L36256 (A54378)	L36021 (A54187)	L36807 (A55144)			
BCKDHB Gene Test	81205 81206 81443	A53600	A55100 A55099	L36021 (A54255)	L36807 (A55145)			
BCR-ABL Negative Myeloproliferative Disease	81206 81207 81208 81219 81270 81279 81338 81339 81450 81479 0027U 0040U	L36044 (A56959)	L36180 (A57421) L36186 (A57422)	L36117 (A56999)	L36815 (A57570)			
BDX-XL2	0080U	L37031 (A56929)	L37054 (A57356)	L37134 (A56947)	L37216 (A57558)			

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For states/territories with no LCDs/LCAs, refer to the applicable Palmetto MolDX Program Guideline for coverage guidelines.

Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
			L37062 (A57357)					
Biomarkers in Cardiovascular Risk Assessment	82172 82610 83090 83695 83698 83700 83701 83704 83719 83721 86141	L36129 (A56943)	L36358 (A57037) L36362 (A57055)	L36139 (A57386)	L36523 (A57559)			
bioTheranostics CancerTYPE ID®	81540	L35025 (A53101)	L35160 (A54386) L36256 (A54388)	L36021 (A54188)	L36807 (A55147)	L35396 (A52986)	L35000 (A56199)	
Lab: Bladder/Urothelial Tumor Markers	88120 88121 86294 86316 86386	L33420 (A53095)	L36678 (A55028) L36680 (A55029)	A56471	L36807 (A56332)			
BLM Gene Analysis	81209 81443	A53540	A55114 A55113	L36021 (A54256)	L36807 (A55148)			
Blood Product Molecular Antigen Typing	81105 81106 81107 81108 81109 81110 81111 81112 81403 0001U 0084U 0180U 0201U 0221U 0222U	L38240 (A58308)	L38331 (A57124) L38333 (A57376)	L38249 (A57155)	L38441 (A57110)			
BluePrint®	81479	A53484	A55116	L36021	L36807			

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Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
			A55115	(A54257)	(A55146)			
Breast Cancer Assay: Prosigna	81520	L36125 (A56949)	L36380 (A57363) L36386 (A57364)	L36425 (A56989)	L36811 (A57560)			
Breast Cancer Index® (BCI) Gene Expression Test	81518	L37794 (A56875)	L37822 (A57773) L37824 (A57774)	L37832 (A56884)	L37913 (A56335)			
BRCA1 and BRCA2 Genetic Testing	81163 81164 81165 81166 81167 81212 81215 81216 81217 81432 81433 81479 0102U 0103U 0129U 0131U 0132U 0133U 0134U 0135U 0136U 0137U 0138U 0157U 0158U 0159U 0160U 0161U 0162U 81162 81445	L36082 (A56854)	L36161 (A57354) L36163 (A57355)	L36456 (A56971)	L36813 (A57771)	L36715 (A56542)		L36499 (A57449)

Molecular Diagnostic Genetic Tests Included in the Palmetto MolDX Program Accessed January 28, 2022 *Also refer to the MACs with corresponding States/Territories. Note: Only use the WPS LCD/LCA if no other Part A LCD/LCA. For states/territories with no LCDs/LCAs, refer to the applicable Palmetto MolDX Program Guideline for coverage guidelines.								
Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
	81455							
CDH1 Genetic Testing	81406	A54835	A55971 A55970	A54878	L36807 (A55622)			
CHD7 Gene Analysis	81407 81479	A53565	A55085 A55086	L36021 (A54243)	L36807 (A55157)			
ConfirmMDx Epigenetic Molecular Assay	81551	L35632 (A56955)	L36327 (A57605) L36329 (A57606)	L36006 (A57031)	L37005 (A55540)			
Controlled Substance Monitoring and Drugs of Abuse Testing	80305 80306 80307 G0480 G0481 G0482 G0483 G0659 0143U 0144U 0145U 0146U 0147U 0148U 0149U 0150U 0227U	L35724 (A54799)	L36707 (A55030) L36668 (A55001)	L36029 (A56818)		L35006 (A56645)		L36393 (A57077)
Corus® CAD Assay	81493	L37612 (A56930)	L37673 (A57415) L37675 (A57416)	A56950	L37770 (A57562)			
Cystatin C Measurement	82610	L37581 (A56948)	L37616 (A57643) L37618 (A57644)	A56988	L37768 (A57563)			L37561 (A57682)
Melanoma Risk Stratification Molecular Testing	81599 81529	L37725 (A56961)	L37748 (A57417) L37750 (A57418)	L38016 (A56990)	L38018 (A56636)			
DecisionDx-UM (Uveal Melanoma)	81552	L37033 (A56906)	L37070 (A57621)	L37130 (A56981)	L37210 (A57566)			

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Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
			L37072 (A57622)					
EndoPredict Breast Cancer Gene Expression Test	81522	L37264 (A56963)	L37295 (A57607) L37311 (A57608)	L37356 (A56997)	L37663 (A57567)			
ENG and ACVRL1 Gene Tests	81405 81406 81479	A53536	A55181 A55182	A54262	L36807 (A55159)			
Envisia, Veracyte, Idiopathic Pulmonary Fibrosis Diagnostic Test	81554	L37857 (A56898)	L37887 (A57419) L37891 (A57420)	L37905 (A56985)	L37919 A57568)			
FANCC Genetic Testing	81242 81412 81443	A53628	A55183 A55184	A54263	L36807 (A55160)			
FDA Approved CLL Companion Diagnostic Test	88374 88377 88271 88275 88291	A56008	A56009 A56013	A56050	A56020			
FDA-Approved BRAF Tests	81210	L35025 (A54018)	L35160 (A54418) L36256 (A54420)	L35349 (A56882) L36021 (A54191)	L36807 (A55161) L36793 (A55135)	L35396 (A52986)	L35000 (A56199)	L34519 (A57451) L34912 (A57439)
FDA-Approved EGFR Tests	81235	L35025 (A54021)	L36256 (A54424) L35160 (A54422)	L36021 (A54192)	L36807 (A55193)	L35396 (A52986)	L35000 (A56199)	L34519 (A57451)
FDA-Approved KRAS Tests	81275	L35025 (A54472)	L35160 (A54498) L36256 (A54500)	L36021 (A56973)	L36807 (A55162)	L35396 (A52986)	L35000 (A56199)	L34519 (A57451)
Foodborne Gastrointestinal Panels Identified by Multiplex Nucleic Acid Amplification (NAATs)	87505 87506 0097U 87507	L37709 (A56593)	L37350 (A56706) L37368 (A56711)	L37364 (A56596)	L37766 (A56637)			
Fragile X	81243 81244	A53638	A55242 A55241	L36021 (A54264)	L36807 (A55163)			

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Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
	81470 81471							
GBA Genetic Testing	81251	A53542	A55243 A55244	L36021 (A54265)	L36807 (A55164)			
GlycoMark® Testing for Glycemic Control	84378 84999	L36761 (A56872)	L36864 (A57237) L36866 (A57238)	L36906 (A56565)				
HAX1 Gene Sequencing	81479	A53619	A55249 A55252	L36021 (A54266)	L36807 (A55165)			
HBB Full Gene Sequencing	81361 81362 81363 81364 81443	A53493	A55253 A55254	L36021 (A54267)	L36807 (A55166)			
HERmark Assay by Monogram	81479	L35025 (A53103)	L35160 (A54437) L36256 (A54439)	L36021 (A54193)	L36807 (A55167)			
HEXA Gene Analysis	81255 81406 81412 81443	A53598	A55255 A55256	L36021 (A54268)	L36807 (A55168)			
HLA-DQB1*06:02 Testing for Narcolepsy	81383	L36464 (A56857)	L36544 (A57441) L36551 (A57465)	L36485 (A56881)	L37003 (A57575)			
HLA Testing for Transplant Histocompatibility	81370 81371 81372 81375 81376 81378 81379 81380 81382	A56859	A57970 A57972	A56885	A57851			
HTTLPR Gene Testing	81479	A53480	A55264 A55265	L36021 (A54269)	L36807 (A55169)			
Hypercoagulability / Thrombophilia (Factor	81240 81241	L36089 (A56899)	L36155 A57423)	L35984 (A56980)	L36400 (A57571)			

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Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
V Leiden, Factor II Prothrombin, and MTHFR)	81291		L36159 (A57424)					
IKBKAP Genetic Testing	81260 81412 81443	A53596	A55612 A55613	L36021 (A54270)	L36807 (A55170)			
Immunohistochemistry (IHC) Indications for Breast Pathology	88342 88341 88360 88361	L35922 (A56838) (A53704) (A55718)	L36353 (A57614) (A55803) (A54597) L36351 (A57611) (A55802) (A57523)	L36021 (A54271) (A56106) (A56536)	L36805 (A55136) (A55739) (A57733)			L36234 (A57708)
Inivata, InVisionFirst, Liquid Biopsy for Patients with Lung Cancer	81479	L37870 (A56924)	L37897 (A57664) L37899 (A57665)	L37903 (A56982)	L37921 (A56333)			
KIF6 Genotype	81479	A53576	A55273 A55272	L36021 (A54272)	L36807 (A55171)			
Know error®	84999	A53554	A55274 A55275	L36021 (A54273)	L36807 (A55172)			
L1CAM Gene Sequencing	81407 81470 81471	A53659	A55277 A55278	L36021 (A54274)	L36807 (A55192)			
LPA-Aspirin Genotype	81479	A53467	A55280 A55279	L36021 (A54275)	L36807 (A55173)			
LPA-Intron 25 Genotype	81479	A53468	A55282 A55281	L36021 (A54276)	L36807 (A55174)			
Lynch Syndrome Testing	81210 81288 81292 81293 81294 81295 81296 81297 81298 81299 81300	L35024 (A54987) (A56072)	L36370 (A54995) (A56103) L36374 (A54996) (A56104)	L35349 (A56882) (A56106)	L36807 L36793 (A55135) (A55161)	L35396 (A52986)	L35000 (A56199)	L34912 (A57450)

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Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
	81301 81317 81318 81319 81403 81432 81433 81435 81436 81445 81455 81479 88341 88342 0101U 0130U 0134U 0157U 0158U 0159U 0160U 0161U 0162U							
MammaPrint	81521	L35025 (A53104)	L36256 (A54447) L35160 (A54445)	L36021 (A54194)	L36807 (A55175)			
MCOLN1 Genetic Testing	81290 81412 81443	A53630	A55283 A55284	L36021 (A54277)	L36807 (A55176)			
MDS FISH	88271 88273 88274 88275 88291	L37602 (A56913)	L37620 (A57661) L37622 (A57662)	L37608 (A56926)	L37772 (A57576)			
MECP2 Genetic Testing	81302 81303 81304 81470 81471	A53574	A55285 A55286	L36021 (A54278)	L36807 (A55189)			

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Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
	81479							
Melanoma Risk Stratification Molecular Testing	81529 81599	L37725 (A56961)	L37748 (A57268) L37750 (A57290)	L38016 (A57165)	L38018 (A56636)			
MGMT Promoter Methylation Analysis	81287	L35974 (A56941)	L36188 (A57432) L36192 (A57433)	L36113 (A56983)	L37001 (A57577)			
Microsatellite Instability-High (MSI-H) and Mismatch Repair Deficient (dMMR) Biomarker for Patients with Unresectable or Metastatic Solid Tumors	81210 81288 81292 81293 81294 81295 81296 81297 81298 81299 81300 81301 81317 81318 81319 81403 81432 81433 81435 81436 81445 81455 81479 88341 88342 0101U 0130U 0134U 0157U 0158U 0159U	L35024 (A56072)	L36370 (A56103) L36374 (A56104)	A56106	L36793 (A56501)			L34912 (A57450) L36234 (A57708)

Molecular Diagnostic Genetic Tests Included in the Palmetto MolDX Program

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Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
	0160U 0161U 0162U							
Minimal Residual Disease Testing for Cancer	81450 81479 81206 81207 81208 81310 81315 81316 81334 81401 0040U	L38779 (A58988) (A58376)	L38816 (A58456) (A58954) L38814 (A58454) (A58953)	L38822 (A58998) (A58434)	L38835 (A59004) (A58468)			
Mitochondrial Nuclear Gene Tests	81479	A53669	A55290 A55291	L36021 (A54288)	L36807 (A55190)			
MMACHC Test	81404	A54035	A55288 A55289	L36021 (A54209)	L36807 (A55191)			
Multiplex Nucleic Acid Amplified Tests for Respiratory Viral Panels	87631 87632 87633 87636 87637 0115U 0151U 0202U 0223U 0225U 0240U 0241U	L37713 (A56851)	L37301 (A57338) L37315 (A57340)	L37348 (A56974)	L37764 (A57579)			
MYPAP™	84999	A53544	A55292 A55293	L36021 (A54290)	L36807 (A55195)			
myPath® Melanoma Assay	81479 0090U	L37859 (A56858)	L37881 (A57627) (L37879 (A57626)	L37907 (A56878)	L37923 (A57580)			
Myriad's BRACAnalysis CDx™	81162	L35025 (A56854) L36082 (A54338)	L36256 (A55294) L35160 (A55295)	L36456 (A54689)	L36813 (A55224)			

Molecular Diagnostic Genetic Tests Included in the Palmetto MolDX Program

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Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
NRAS Genetic Testing	81311 81479	L35073 (A56962)	L36335 (A57486) L36339 (A57487)	L35442 (A56998)	L36797 (A57581)			
NSD1 Gene Tests	81405 81406 81479	A53585	A55609 A55615	L36021 (A54291)	L36807 (A55198)			
Oncotype DX® Breast Cancer for DCIS (Genomic Health™)	0045U	L36912 (A56870)	L36941 (A57619) L36947 (A57620)	L36951 (A56887)	L37199 (A57583)			
Oncotype DX Breast Cancer Assay	81519	L35025 (A53105)	L36256 (A54482) L35160 (A54480)	L36021 (A54195)	L36807 (A55230)			
Oncotype DX Colon Cancer Assay	81525	L35025 (A53106)	L36256 (A54486) L35160 (A54484)	L36021 (A54196)	L36807 (A55231)	L35396 (A52986)	L35000 (A56199)	
PAX6 Gene Sequencing	81479	A53664	A55625 A55632	L36021 (A54293)	L36807 (A55199)			
Percepta® Bronchial Genomic Classifier	81479	L36854 (A56849)	L36886 (A57502) L36891 (A57504)	L36908 (A56972)	L37195 (A57584)			
Pharmacogenomics Testing	81220 81225 81226 81227 81231 81232 81247 81283 81306 81328 81335 81350 81355 81374 81377	L38294 (A58318)	L38335 (A57384) L38337 (A57385)	L38394 (A58324)	L38435 (A58395) L36807 (A57772)	L35396 (A56541)		

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Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
	81381 81383 81406 81479 0030U 0070U 0071U 0072U 0073U 0074U 0075U 0076U							
Phenotypic Biomarker Detection in Circulating Tumor Cells	81479	L38566 (A58021)	L38643 (A58183) L38645 (A58185)	L38584 (A58063)	L38678 (A58205)			
Pigmented Lesion Assay	0089U	L38051 (A57868)	L38151 (A58052) L38153 (A58053)	L38111 (A57915)	L38178 (A57983)			
PIK3CA Gene Tests	81309 0155U	A53558	A55597 A55602	L36021 (A54295)	L36807 (A55200)			
Plasma-Based Genomic Profiling in Solid Tumors	81479 81445	L38043 (A57867)		L38065 (A57917)	L38168 (A57936)			
PreDx®	81506	A53489	A55594 A55599	L36021 (A54296)	L36807 (A55201)			
Progensa® PCA3 Assay	81313 0113U	L35025 (A53107) (A56853)	L36256 (A54492) (A57527) L35160 (A54489) (A57526)	L36021 (A54197) (A56973)	L36807 (A55202) (A57772)	L35396 (A52986)	L35000 (A56199)	L34519 (A57451)
Prognostic and Predictive Molecular Classifiers for Bladder Cancer	81401 81403 81404 81445 81479 0016M	L38576 (A58028)	L38647 (A58181) L38649 (A58187)	L38586 (A58065)	L38684 (A58211)			

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Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
ProMark Risk Score	81479	L36665 (A56957)	L36704 (A57515) L36706 (A57609)	L36675 (A57034)	L37011 (A57587)			
Prometheus IBD sgi Diagnostic Policy	81479 82397 83520 86140	L37260 (A56933)	L37299 (A57516) L37313 (A57517)	L37352 (A56940)	L37539 (A57588)			
Prostate Cancer Genomic Classifier Assay for Men with Localized Disease	81541 81542	L38292 (A58343)	L35160 (A57526) L36256 (A57527)	L38303 (A58371)	L38433 (A57106)			
PTCH1 Gene Testing	81479	A53567	A55608 A55618	L36021 (A54297)	L36807 (A55203)			
ResponseDx Tissue of Origin®	81504	L35025 (A53108)	L36256 (A54496) L35160 (A54494)	L36021 (A54198)	L36807 (A55204)		L35000 (A56199)	
RPS19 Gene Tests	81405 81479	A53587	A55610 A55614	L36021 (A54299)	L36807 (A55205)			
SEPT9 Gene Test	81327	A53702	A55623 A55628	L36021 (A54300)	L36807 (A55206)			
SMPD1 Genetic Testing	81330 81412	A53624	A55627 A55631	L36021 (A54285)	L36807 (A55208)			
STAT3 Gene Testing	81405	A53562	A55480 A55481	L36021 (A54284)	L36807 (A55209)			
SULT4A1 Genetic Testing	81479	A53538	A55596 A55601	L36021 (A54283)	L36807 (A55210)			
TERC Gene Tests	81479	A53589	A55611 A55616	L36021 (A54282)	L36807 (A55211)			
ThermoFisher Oncomine Dx Target Test For Non-Small Cell Lung Cancer	0022U	L35025 (A55822)	L36256 (A55881) L35160 (A55888)	L36021 (A55851)	L36807 (A55846)	L35396 (A52986)		
TP53 Gene Test	81404 81405	A53591	A55487 A55484	L36021 (A54281)	L36807 (A55221)			
UGT1A1 Gene Analysis	81350	L35025 (A56853)	L36256 (A57527)	L36021 (A56973)	L36807 (A57772)			

Molecular Diagnostic Genetic Tests Included in the Palmetto MolDX Program Accessed January 28, 2022 *Also refer to the MACs with corresponding States/Territories. Note: Only use the WPS LCD/LCA if no other Part A LCD/LCA. For states/territories with no LCDs/LCAs, refer to the applicable Palmetto MolDX Program Guideline for coverage guidelines.								
Test	Code	Palmetto MolDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
			L35160 (A57526)					
Vectra™ DA	81490	L35025 (A53110)	L36256 (A54505) L35160 (A54503)	L36021 (A54201)	L36807 (A55223)	L35062 (A56541)		
VEGFR2 Tests	81479	A53548	A55468 A55469	L36021 (A54279)	L36807 (A55232)			

Molecular Diagnostic Genetic Tests Included in the Palmetto MolDX Program Accessed January 28, 2022 *Also refer to the MACs with corresponding States/Territories. Note: Only use the WPS LCD/LCA if no other Part A LCD/LCA. For states/territories with no LCDs/LCAs, refer to the applicable Palmetto MolDX Program Guideline for coverage guideline.	
Part A and B MACs	States/Territories
CGS Administrators, LLC	KY, OH
First Coast Service Options, Inc.	FL, PR, VI
National Government Services, Inc.	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian Healthcare Solutions, LLC	AK, AS, AZ, CA, HI, ID, MP, MT, ND, NV, OR, SD, UT, WA, WY
Novitas Solutions, Inc	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
Palmetto, GBA	AL, GA, NC, SC, TN, VA, WV
Wisconsin Physicians Service Insurance Corporation	AK, AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY
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MyPRS™ Test for Multiple Myeloma Gene Expression Profile Accessed January 28, 2022				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L35396 (A52986)	Biomarkers for Oncology	Part A and B MAC	Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
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Policy History/Revision Information

Date	Summary of Changes
02/15/2022	Supporting Information • Revised list of *Molecular Diagnostic Genetic Tests Included in the Palmetto MolDX Program*

Date	Summary of Changes
	○ Added: ▪ Minimal Residual Disease Testing for Cancer ○ Removed: ▪ Minimal Residual Disease Testing for Colorectal Cancer ▪ ClonoSEQ® Assay for Assessment of Minimal Residual Disease (MRD) in Patients with Specific Lymphoid Malignancies **Supporting Information** • Updated list of available Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) to reflect the most current reference links • Archived previous policy version MCS040.04

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