

Molecular Pathology/Molecular Diagnostics/Genetic Testing

Policy Number: MCS040.12
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[➔ Instructions for Use](#)

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Coverage Guidelines

Molecular pathology, molecular diagnostics, genetic testing, and counseling are covered when Medicare coverage criteria are met.

Notes:

- The guidelines in this Coverage Summary are for specific procedures only. For procedures not addressed in this Coverage Summary, refer to the [Medicare Coverage Database](#) to search for applicable coverage policies (National Coverage Determinations, Local Coverage Determinations and Local Coverage Articles).
- 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 March 4, 2024)

Molecular Diagnostic Genetic Tests Included in the Palmetto MoIDX Program

Refer to the [Molecular Diagnostic Genetic Tests included in the Palmetto MoIDX Program](#) table for specific LCDs/LCAs and applicable coverage guidelines.

Note: The [Molecular Diagnostic Genetic Tests included in the Palmetto MoIDX Program](#) table is a list, but not all-inclusive, of tests that have completed the MoIDX Technical Assessment Process. For the most current MoIDX information go to [MoIDX 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 Solid Tumor 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 March 4, 2024)

Vectra™ DA (CPT Code 81490)

Medicare does not have a National Coverage Determination (NCD) for Vectra DA. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at <https://www.cms.gov/medicare-coverage-database/search.aspx>.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy titled [Omnibus Codes](#).

Note: After searching the [Medicare Coverage Database](#), if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

(Accessed March 4, 2024)

Supporting Information

Molecular Diagnostic Genetic Tests Included in the Palmetto MoIDX Program

Accessed April 12, 2024

*Also refer to the [MACs with corresponding States/Territories](#).

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

Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
4Kscore® Assay	81539	L36763 (A56932) L35025 (A59636)	L35160 (A59641) L36256 (A59642)	L36021 (A59646)	L36807 (A59649)	L37792 (A56653) L35062 (A58917)	A56609	L37798 (A56287) L34519 (A58918)
4q25-AF Risk Genotype Testing	81479	A53457	A55091 A55090	L36021 (A54241)	L36807 (A55137)		L35000 (A56199)	
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) (A58918)
ABL1 Gene Analysis	81170	L35025 (A56853)	L36256 (A57527) L35160 (A57526)	L36021 (A56973)	L36807 (A57772)	L35396 (A52986)	L35000 (A56199)	L34519 (A57451) (A58918)
Afirma™ Assay by Veracyte	81546	L35025 (A53098)	L35160 (A54356) L36256 (A54358)	L36021 (A54185)	L36807 (A55139)	L35396 (A52986)	L38968 (A58656)	L34519 (A58918)
ApoE Genotype	81401	A53652	L36358 (A55094) L36362 (A55095)	L36021 (A54244)	L36807 (A55141)	L39082 (A52795)	L35000 (A56199)	L34519 (A57451) (A58918)
Aspartoacylase 2 Deficiency (ASPA) Testing	81200 81412 81443 81479	A53602	A55089 A55088	L36021 (A54253)	L36807 (A55142)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
ATP7B Gene Tests	81406 81443 81479	A53550	A55097 A55098	L36021 (A54254)	L36807 (A55143)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
BCKDHB Gene Test	81205 81206 81443	A53600	A55100 A55099	L36021 (A54255)	L36807 (A55145)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918) (A57451)

Molecular Diagnostic Genetic Tests Included in the Palmetto MoIDX Program

Accessed April 12, 2024

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

Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
BCR-ABL Negative Myeloproliferative Disease	81206	L36044	L36180	L36117	L36815	L35062	L35000	L34519
	81207	(A56959)	(A57421)	(A56999)	(A57570)	(A58917)	(A56199)	(A58918)
	81208		L36186					
	81219		(A57422)					
	81270							
	81279							
	81338							
	81339							
	81450							
	81479							
0027U								
	0040U	L36044 (A56959)	L36180 (A57421) L36186 (A57422)	L36117 (A56999)	L36815 (A57570)	L35062 (A58917)		L34519 (A58918)
BDX-XL2	0080U	L37031 (A56929)	L37054 (A57356) L37062 (A57357)	L36021 (A59646)	L37216 (A57558)			
Biomarkers in Cardiovascular Risk Assessment	82172	L36129	L36358	L36139	L36523			
	83695	(A56943)	(A57037)	(A57386)	(A57559)			
	83700		L36362					
	83701		(A57055)					
	83704							
	83719							
	86141	L36129 (A56943)	L36358 (A57037) L36362 (A57055)	L36139 (A57386)	L36523 (A57559)	L34856 (A56643)		L33908 (A57803)
	83721	L36129 (A56943)	L36358 (A57037) L36362 (A57055)	L36139 (A57386)	L36523 (A57559)	L35099 (A56420)		
82610	L36129 (A56943) L37581 (A56948)	L36358 (A57037) L36362 (A57055) L37616 (A57643) L37618	L36139 (A57386) L37598 (A56988)	L36523 (A57559)			L37561 (A57682)	

Molecular Diagnostic Genetic Tests Included in the Palmetto MoIDX Program

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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Biomarkers in Cardiovascular Risk Assessment			(A57644)					L37561 (A57682)
	83090	L36129 (A56943) L37581 (A56948)	L37616 (A57643) L37618 (A57644)	L36139 (A57386)	L36523 (A57559)	L34914 (A56416)		
	81439	L36129 (A53605)	L36358 (A54975) L36362 (A54976)	L36139 (A54685)	L36523 (A55235)	L39082 (A58795)	L35000 (A56199)	
	83698	L36129 (A56943)	L36358 (A57037) L36362 (A57055)	L36139 (A57386)	L36523 (A57559)	L34914 (A56416)		
bioTheranostics CancerTYPE ID®	81540	L35025 (A53101)	L35160 (A54386) L36256 (A54388)	L36021 (A54188)	L36807 (A55147)	L35396 (A52986)	L35000 (A56199)	L34519 (A58918)
Lab: Bladder/Urothelial Tumor Markers	88120 88121 86294 86316 86386	L33420 (A53095)	L36678 (A55028) L36680 (A55029)	L36975 (A56471)	L36807 (A56332)			
	88120 88121	L33420 (A53095)	L36678 (A55028) L36680 (A55029)	L36975 (A56471)	L36807 (A56332)	L35396 (A52986)		
BLM Gene Analysis	81209 81443	A53540	A55114 A55113	L36021 (A54256)	L36807 (A55148)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918) (A57451)
Blood Product Molecular Antigen Typing	81105 81106 81107 81108 81109 81110 81111 81112 81403	L38240 (A58308)	L38331 (A57124) L38333 (A57376)	L38249 (A57155)	L38441 (A57110)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
	0001U	L38240	L38331	L38249	L38441	L35062		L34519

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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Blood Product Molecular Antigen Typing	0084U	(A58308)	(A57124)	(A57155)	(A57110)	(A58917)		(A58918)
	0180U		L38333					L39073
	0181U		(A57376)					(A58812)
	0182U							
	0183U							
	0184U							
	0185U							
	0186U							
	0187U							
	0188U							
	0189U							
	0190U							
	0191U							
	0192U							
	0194U							
	0195U							
	0196U							
	0197U							
	0198U							
	0199U							
0200U								
0201U								
0221U								
0222U								
	0193U	L38240 (A58308)	L38331 (A57124)	L38249 (A57155)	L38441 (A57110)	L39063 (A58801)		L34519 (A58918)
		L38274 (A58017)	L38333 (A57376)	L36021 (A56973)	L36807 (A57772)	L35062 (A58917)		
BluePrint®	81479	A53484	A55116 A55115	L36021 (A54257)	L36807 (A55146)			
Breast Cancer Assay: Prosigna	81520	L36125 (A56949)	L36380 (A57363) L36386 (A57364)	L36425 (A56989)	L36811 (A57560)	L35396 (A52986)	L35000 (A56199)	L34519 (A58918)
Breast Cancer Index® (BCI) Gene Expression Test	81518	L37794 (A56875)	L37822 (A57773) L37824 (A57774)	L37832 (A56884)	L37913 (A56335)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
CDH1 Genetic Testing	81406	A54835	A55971 A55970	A54878	L36807 (A55622)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)

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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					
			Noridian	CGS	WPS	Novitas	NGS	First Coast
CHD7 Gene Analysis	81407 81479	A53565	A55085 A55086	L36021 (A54243)	L36807 (A55157)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
DecisionDx-UM (Uveal Melanoma)	81552	L37033 (A56906)	L37070 (A57621) L37072 (A57622)	L37130 (A56981)	L37210 (A57566)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
EndoPredict Breast Cancer Gene Expression Test	81522	L37264 (A56963)	L37295 (A57607) L37311 (A57608)	L37356 (A56997)	L37663 (A57567)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
ENG and ACVRL1 Gene Tests	81405 81406 81479	A53536	A55181 A55182	A54262	L36807 (A55159)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
Envisia™, Veracyte™, Idiopathic Pulmonary Fibrosis Diagnostic Test	81554	L37857 (A56898)	L37887 (A57419) L37891 (A57420)	L37905 (A56985)	L37919 A57568)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
FANCC Genetic Testing	81242 81412 81443	A53628	A55183 A55184	A54263	L36807 (A55160)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
FDA-Approved BRAF Tests	81210	L35025 (A54018)	L35160 (A54418) L36256 (A54420)	L36021 (A54191)	L36807 (A55161)	L35396 (A52986)	L35000 (A56199)	L34519 (A57451) (A58918)
FDA-Approved EGFR Tests	81235	L35025 (A54021)	L36256 (A54424) L35160 (A54422)	L36021 (A54192)	L36807 (A55193)	L35396 (A52986)	L35000 (A56199)	L34519 (A57451) (A58918)
FDA-Approved KRAS Tests	81275 81276 81479	L35025 (A54472)	L35160 (A57527) L36256 (A57526)	L36021 (A54688)	L36807 (A55162)	L35396 (A52986)	L35000 (A56199)	L34519 (A57451) (A58918)
Fragile X	81243 81244 81470 81471	A53638	A55242 A55241	L36021 (A54264)	L36807 (A55163)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
GBA Genetic Testing	81251	A53542	A55243 A55244	L36021 (A54265)	L36807 (A55164)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918) (A57451)

Molecular Diagnostic Genetic Tests Included in the Palmetto MoIDX Program

Accessed April 12, 2024

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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Germline testing for use of PARP inhibitors	81162 81479	A54338	A55294 A55295	A54689	A55224	L35062 (A58917)	L35000 (A56199)	L34519 (A58918) (A57451)
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)		L35000 (A56199)	
HBB Gene Test	81361 81362 81363 81364 81443	A53493	A55253 A55254	L36021 (A54267)	L36807 (A55166)	L35062 (A58917)	L35000 (A56199)	L34519 (A57451) (A58918)
HEXA Gene Analysis	81255 81406 81412 81443	A53598	A55255 A55256	L36021 (A54268)	L36807 (A55168)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
HLA-DQB1*06:02 Testing for Narcolepsy	81383	L36464 (A56857)	L36544 (A57441) L36551 (A57465)	L36485 (A56881)	L37003 (A57575)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
HLA Testing for Transplant Histocompatibility	81370 81371 81372 81373 81375 81376 81378 81379 81380 81382	A56859	A57970 A57972	A56885	A57851	L35062 (A58917) L39063 (A56541)	L35000 (A56199)	L34519 (A58918)
HTTLPR Gene Testing	81479	A53480	A55264 A55265	L36021 (A54269)	L36807 (A55169)			
Hypercoagulability/Thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR)	81240 81241 81291	L36089 (A56899)	L36155 A57423) L36159 (A57424)	L35984 (A56980)	L36400 (A57571)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918) (A57451)

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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
IKBKAP Genetic Testing	81260	A53596	A55612	L36021	L36807	L35062	L35000	L34519
	81412		A55613	(A54270)	(A55170)	(A58917)	(A56199)	(A58918)
	81443							(A57451)
Immunohistochemistry (IHC) Indications for Breast Pathology	88312	L35922	L36353		L36805			
	88313	(A56838)	(A57614)		(A57733)			
			L36351					
			(A57611)					
	88341	L35025	L36353	L35986	L36805			L34912
	88342	(A56072)	(A57614)	(A59292)	(A57733)			(A57450)
		L35922	L36351	L36021	(A55136)			
		(A53704)	(A57611)	(A54271)				
		(A56838)	L36351					
			(A57523)					
			L36353					
			(A57797)					
88360	L35922	L36353	L35986	L36805				
88361	(A53704)	(A57614)	(A59292)	(A57733)				
	(A56838)	L36351	L36021	(A55136)				
		(A57611)	(A54271)					
			L36351					
			(A57523)					
			L36353					
			(A57797)					
Inivata™, InVisionFirst®, Liquid Biopsy for Patients with Lung Cancer	81479 0388U	L37870 (A56924)	L37897 (A57664)	L37903 (A56982)	L37921 (A56333)	L35062 (A58917)		L34519 (A58918)
KIF6 Genotype	81479	A53576	A55273 A55272	L36021 (A54272)	L36807 (A55171)		L35000 (A56199)	
Know error®	84999	A53554	A55274 A55275	L36021 (A54273)	L36807 (A55172)			
Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer	0101U	L38966	L38972	L39017	L39040	L35062	L35000	L34519
	0102U	(A58652)	(A58679)	(A58734)	(A58756)	(A58917)	(A56199)	(A58918)
	81163		L38974					
	81164		(A58681)					
	81165							
	81166							
	81167							
	81201							
81202								

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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer	81203	L38966	L38972	L39017	L39040	L35062	L35000	L34519
	81212	(A58652)	(A58679)	(A58734)	(A58756)	(A58917)	(A56199)	(A58918)
	81215		L38974					
	81216		(A58681)					
	81217							
	81293							
	81292							
	81294							
	81295							
	81296							
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	81298							
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	81308							
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	81319							
	81321							
	81322							
	81323							
	81351							
	81353							
	81403							
	81404							
	81405							
81406								
81432								
81433								
81435								
81436								
81437								
81438								
81479								
	0103U	L38966 (A58652)	L38972 (A58679) L38974 (A58681)	L39017 (A58734)	L39040 (A58756)	L35062 (A58917)		L34519 (A58918)

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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Lab-Developed Tests for Inherited Cancer Syndromes in Patients with Cancer	0129U	L38966 (A58652)	L38972 (A58679) L38974 (A58681)	L39017 (A58734)	L39040 (A58756)	L35062 (A58917)		L34519 (A58918)
L1CAM Gene Sequencing	81407 81470 81471	A53659	A55277 A55278	L36021 (A54274)	L36807 (A55192)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
LPA-Aspirin Genotype	81479	A53467	A55280 A55279	L36021 (A54275)	L36807 (A55173)			
LPA-Intron 25 Genotype	81479	A53468	A55282 A55281	L36021 (A54276)	L36807 (A55174)		L35000 (A56199)	
MammaPrint	81521	L35025 (A53104)	L36256 (A54447) L35160 (A54445)	L36021 (A54194)	L36807 (A55175)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
MCOLN1 Genetic Testing	81290 81412 81443	A53630	A55283 A55284	L36021 (A54277)	L36807 (A55176)	L35062 (A58917) (A56541)	L35000 (A56199)	L34519 (A58918)
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 81479	A53574	A55285 A55286	L36021 (A54278)	L36807 (A55189)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
Melanoma Risk Stratification Molecular Testing	81479 81529 81599	L37725 (A56961)	L37748 (A57290) L37750 (A57268)	L38016 (A57165)	L38018 (A56636)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
MGMT Promoter Methylation Analysis	81287	L35974 (A56941)	L36188 (A57432) L36192 (A57433)	L36113 (A56983)	L37001 (A57577)	L35062 (A58917)	L35000 (A56199)	L34519 (A57451) (A58918)
Microsatellite Instability-High (MSI-H) and Mismatch Repair	81301 81479	L35025 (A56072)	L35160 (A56103) L36256	L36021 (A56106)	L36807 (A57772)	L35396 (A52986)	L35000 (A56199)	L34912 (A57450)

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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Deficient (dMMR) Biomarker for Patients with Unresectable or Metastatic Solid Tumors			(A56104)					
	88341 88342	L35025 (A56072) L35922 (A53704) (A56838)	L35160 (A56103) L36256 (A56104)	L36021 (A56106)	L36805 (A57733) (A55136)			L34912 (A57450)
Minimal Residual Disease Testing for Cancer	81445	L38779	L38816	L38822	L38835	L35062	L37810	L34519
	81479	(A58376)	(A58456)	(A58434)	(A58468)	(A58917)	(A56867)	(A58918)
	0340U 0356U 0422U		L38814 (A58454)					
	0340U 0356U 0422U	L38779 (A58376)	L38816 (A58456) L38814 (A58454)	L38822 (A58434)	L38835 (A58468)	L35062 (A58917)		L34519 (A58918)
Mitochondrial Nuclear Gene Tests	81479	A53669	A55290 A55291	L36021 (A54288)	L36807 (A55190)		L35000 (A56199)	
MMACHC Test	81404	A54035	A55288 A55289	L36021 (A54209)	L36807 (A55191)	L35062 (A58917)	L35000 (A56199)	L34519 (A57451) (A58918)
Molecular Assays for the Diagnosis of Cutaneous Melanoma	0090U	L39345	L39375	L39389	L39479	L35062		L34519
	0314U 81479	(A59109)	(A59181) L39373 (A59179)	(A59163)	(A59261)	(A58917)		(A58918)
Molecular Biomarker Testing to Guide Targeted Therapy Selection in Rheumatoid Arthritis	81599	L39424 (A59484)	L39467 (A59521) L39469 (A59522)	L39427 (A59529)	L39481 (A59536)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
Molecular Biomarkers to Risk-Stratify Patients at Increased Risk for Prostate Cancer	81313	L38985	L39007	L38997	L39042	L35062	L37733	L34519
	81479	(A58700)	(A58724)	(A58713)	(A58759)	(A58917)	(A56609)	(A58918)
	81551 0005U		L39005 (A58718)					
	0339U	L38985 (A58700)	L39007 (A58724) L39005 (A58718)	L38997 (A58713)	L39042 (A58759)	L35062 (A58917)		L34519 (A58918)

Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	U0001	L38988	L39003	L39038	L39044			
	U0002	(A58710)	(A58726)	(A58747)	(A58761)			
	0352U		L39001					
	0353U		(A58720)					
	0402U							
	0429U							
	87149							
	87150							
	87153							
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Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	87529	L38988	L39003	L39038	L39044			
	87530	(A58710)	(A58726)	(A58747)	(A58761)			
	87531		L39001					
	87532		(A58720)					
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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Molecular Syndromic Panels for Infectious Disease Pathogen Identification Testing	87999	L38988 (A58710)	L39003 (A58726) L39001 (A58720)	L39038 (A58747)	L39044 (A58761)			
	87505 87506 87507	L38988 (A58710)	L39003 (A58726) L39001 (A58720)	L39038 (A58747)	L39044 (A58761)	L38229 (A56642)	L39226 (A58663)	L38227 (A56638)
	87631 87632 87633 87636 87637 0115U 0202U 0223U 0225U 0240U 0241U	L38988 (A58710)	L39003 (A58726) L39001 (A58720)	L39038 (A58747)	L39044 (A58761)	L38916 (A58575)	L39027 (A58741)	L38918 (A58577)
	81513 81514	L38988 (A58710)	L39003 (A58726) L39001 (A58720)	L39038 (A58747)	L39044 (A58761)	L35062 (A58917)		L34519 (A58918)
	81479 0114U	L39256 (A59015)	L39262 (A59032) L39264 (A59034)	L39276 (A59051)	L39356 (A59121)	L35062 (A58917)		L34519 (A58918)
	81479 81595 81599	L38568 (A58019)	L38671 (A58170) L38629 (A58168)	L38582 (A58061)	L38680 (A58207)	L35062 (A58917)		L34519 (A58918)
	0118U	L38568 (A58019)	L38671 (A58170) L38629 (A58168)	L38582 (A58061)	L38680 (A58207)	L35062 (A58917)		L34519 (A58918)
	MYPAP™	84999	A53544	A55292 A55293	L36021 (A54290)	L36807 (A55195)		

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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Next-Generation Sequencing for Solid Tumors	81445	L38045	L38119	L38067	L38158	L35062	L37810	L34519
	81449	(A57831)	(A57901)	(A57870)	(A57858)	(A58917)	(A56867)	(A58918)
	81457		L38121					
	81458		(A57905)					
	81459							
	81479							
	0244U							
	0250U							
	0329U							
	0334U							
0379U								
0391U								
Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	81450	L38047	L38123	L38070	L38176	L35062	L37606	L34519
	81451	(A57837)	(A57891)	(A57873)	(A57878)	(A58917)	(A56793)	(A58918)
	81479		L38125					
			(A57892)					
NRAS Genetic Testing	81311	L35073	L36335	L35442	L36797	L35062	L35000	L34519
	81479	(A56962)	(A57486)	(A56998)	(A57581)	(A58917)	(A56199)	(A57451)
			L36339					(A58918)
			(A57487)					
NSD1 Gene Tests	81405	A53585	A55609	L36021	L36807	L35062	L35000	L34519
	81406		A55615	(A54291)	(A55198)	(A58917)	(A56199)	(A58918)
	81479							
Oncotype DX® Breast Cancer for DCIS (Genomic Health™)	0045U	L36912	L36941	L36951	L37199	L35062		L34519
		(A56870)	(A57619)	(A56887)	(A57583)	(A58917)		(A58918)
			L36947					
			(A57620)					
Oncotype DX Breast Cancer Assay	81519	L35025	L36256	L36021	L36807	L35062	L35000	L34519
		(A53105)	(A54482)	(A54195)	(A55230)	(A58917)	(A56199)	(A58918)
			L35160					
			(A54480)					
Oncotype DX Colon Cancer Assay	81525	L35025	L36256	L36021	L36807	L35396	L35000	L34519
		(A53106)	(A54486)	(A54196)	(A55231)	(A52986)	(A56199)	(A58918)
			L35160					
			(A54484)					
PAX6 Gene Sequencing	81479	A53664	A55625	L36021	L36807	L35062		
			A55632	(A54293)	(A55199)	(A58917)		

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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Percepta® Bronchial Genomic Classifier	81479	L36854 (A56849)	L36886 (A57502) L36891 (A57504)	L36908 (A56972)	L37195 (A57584)	L35062 (A58917)		
Pharmacogenomics Testing	81225	L38294 (A58318)	L38335 (A57384)	L38394 (A58324)	L38435 (A58395)	L39063 (A58801)	L35000 (A56199)	L39073 (A58812)
	81226							
	81227	L35025 (A56853)	L38337 (A57385)	L36021 (A56973)	L36807 (A57772)	L35062 (A58917)		L34519 (A58918)
	81231							
	81232		L36256 (A57527)					
	81247							
	81283		L35160 (A57526)					
	81306							
	81328							
	81335							
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	81374							
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	81381							
	81383							
	81401							
	81406							
	81418							
	81479							
	0029U	L38294 (A58318)	L38335 (A57384)	L38394 (A58324)	L38435 (A58395)	L39063 (A58801)		L39073 (A58812)
	0030U							
	0034U	L35025 (A56853)	L38337 (A57385)	L36021 (A56973)	L36807 (A57772)	L35062 (A58917)		L34519 (A58918)
	0071U							
	0076U		L36256 (A57527)					
	0286U							
	0345U		L35160 (A57526)					
	0380U							
	0411U							
	0419U							
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)	L35062 (A58917)		L34519 (A58918)

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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
PIK3CA Gene Tests	81309	A53558	A55597 A55602	L36021 (A54295)	L36807 (A55200)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918) (A57451)
	0155U	A53558	A55597 A55602	L36021 (A54295)	L36807 (A55200)	L35062 (A58917)		L34519 (A58918) (A57451)
Plasma-Based Genomic Profiling in Solid Tumors	81479	L38043	L39230	L38065	L38168	L35062		L34519
	0179U	(A57867)	(A58973)	(A57917)	(A57936)	(A58917)		(A58918)
	0326U		L39232	L36021				
	0409U		(A58975)	(A56973)				
	0428U	L38043 (A57867)	L39230 (A58973)	L38065 (A57917)	L38168 (A57936)	L35062 (A58917)		L34519 (A58918)
81445	L38576 (A58028)	L38647 (A58181) L38649 (A58187)	L38586 (A58065)	L38684 (A58211)	L35062 (A58917)	L37810 (A56867)	L34519 (A58918)	
Predictive Classifiers for Early Stage Non-Small Cell Lung Cancer	81479	L38238	L38327	L38284	L38443	L35062		L34519
	0288U	(A58031)	(A57329) L38329 (A57330)	(A58038)	(A57112)	(A58917)		(A58918)
Prognostic and Predictive Molecular Classifiers for Bladder Cancer	81401	L38576	L38647	L38586	L38684	L35062	L35000	L34519
	81403	(A58028)	(A58181)	(A58065)	(A58211)	(A58917)	(A56199)	(A58918)
	81404		L38649					
	81479		(A58187)					
	81445	L38576 (A58028)	L38647 (A58181) L38649 (A58187)	L38586 (A58065)	L38684 (A58211)	L35062 (A58917)	L37810 (A56867)	L34519 (A58918)
0016M	L38576 (A58028)	L38647 (A58181) L38649 (A58187)	L38586 (A58065)	L38684 (A58211)	L35062 (A58917)		L34519 (A58918)	
ProMark® Risk Score	81479	L36665 (A56957)	L36704 (A57515) L36706 (A57609)	L36675 (A57034)	L37011 (A57587)	L35062 (A58917)		

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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Prometheus IBD sgi Diagnostic® Policy	81479	L37260 (A56933)	L37299 (A57516) L37313 (A57517)	L37352 (A56940)	L37539 (A57588)			
Prostate Cancer Genomic Classifier Assay for Men with Localized Disease	81541	L38292 (A58343)	L35160 (A57526)	L38303 (A58371)	L38433 (A57106)	L35062 (A58917)	L35000 (A56199)	L34519 (A58918)
	81542		L36256 (A57527)					
	0047U	L38292 (A58343)	L35160 (A57526)	L38303 (A58371)	L38433 (A57106)	L35062 (A58917)		L34519 (A58918)
Proteomics Testing	81490	L35025 (A59636)	L35160 (A59641)	L36021 (A59646)	L36807 (A59649)	L35062 (A58917)	L38371 (A57020)	L34519 (A58918)
	81500		L36256 (A59642)					
	81503							
	81517							
	81539							
	81599							
	0002M	L35025 (A59636)	L35160 (A59641)	L36021 (A59646)	L36807 (A59649)	L35062 (A58917)		L34519 (A58918)
	0003M		L36256 (A59642)					
	0015M							
	0019M							
	0002U							
	0003U							
	0021U							
	0080U							
	0092U							
	0095U							
	0105U							
	0117U							
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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Proteomics Testing	0312U	L35025	L35160	L36021	L36807	L35062		L34519
	0322U	(A59636)	(A59641)	(A59646)	(A59649)	(A58917)		(A58918)
	0344U		L36256					
	0351U		(A59642)					
	0360U							
	0365U							
	0366U							
	0367U							
	0375U							
	0384U							
	0385U							
	0387U							
	0407U							
	0415U							
	0436U							
	0117U	L35025 (A59636)	L35160 (A59641) L36256 (A59642)	L36021 (A59646)	L36807 (A59649)	L39063 (A58801)		L34519 (A58918) L39073 (A58812)
PTCH1 Gene Testing	81479	A53567	A55608 A55618	L36021 (A54297)	L36807 (A55203)			
Repeat Germline Testing	81105	L38274	L38353	L38288	L38429	L35062	L35000	L34519
	81106	(A58017)	(A57332)	(A57141)	(A57100)	(A58917)	(A56199)	(A58918)
	81107		L38351					
	81108		(A57331)					
	81109							
	81110							
	81111							
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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Repeat Germline Testing	81178	L38274	L38353	L38288	L38429	L35062	L35000	L34519
	81179	(A58017)	(A57332)	(A57141)	(A57100)	(A58917)	(A56199)	(A58918)
	81180		L38351					
	81181		(A57331)					
	81182							
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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Repeat Germline Testing	81240	L38274	L38353	L38288	L38429	L35062	L35000	L34519
	81241	(A58017)	(A57332)	(A57141)	(A57100)	(A58917)	(A56199)	(A58918)
	81242		L38351					
	81243		(A57331)					
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Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Repeat Germline Testing	81304	L38274	L38353	L38288	L38429	L35062	L35000	L34519
	81306	(A58017)	(A57332)	(A57141)	(A57100)	(A58917)	(A56199)	(A58918)
	81307		L38351					
	81309		(A57331)					
	81312							
	81317							
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81407								
81408								

Molecular Diagnostic Genetic Tests Included in the Palmetto MoIDX Program

Accessed April 12, 2024

*Also refer to the [MACs with corresponding States/Territories](#).

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

Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Repeat Germline Testing	81410	L38274	L38353	L38288	L38429	L35062	L35000	L34519
	81411	(A58017)	(A57332)	(A57141)	(A57100)	(A58917)	(A56199)	(A58918)
	81412		L38351					
	81413		(A57331)					
	81414							
	81415							
	81416							
	81417							
	81418							
	81419							
	81420							
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0004M								
0001U								
0029U								
0030U								
0031U								

Molecular Diagnostic Genetic Tests Included in the Palmetto MoIDX Program

Accessed April 12, 2024

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

Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Repeat Germline Testing	0032U	L38274	L38353	L38288	L38429	L35062	L35000	L34519
	0033U	(A58017)	(A57332)	(A57141)	(A57100)	(A58917)	(A56199)	(A58918)
	0034U		L38351					
	0070U		(A57331)					
	0071U							
	0072U							
	0073U							
	0074U							
	0075U							
	0076U							
	0078U							
	0079U							
	0084U							
	0094U							
	0101U							
	0102U							
	0103U							
	0129U							
	0130U							
	0131U							
	0132U							
	0133U							
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0170U								
0173U								
0175U								
0180U								
0181U								
0182U								

Molecular Diagnostic Genetic Tests Included in the Palmetto MoIDX Program

Accessed April 12, 2024

*Also refer to the [MACs with corresponding States/Territories](#).

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

Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Repeat Germline Testing	0183U	L38274	L38353	L38288	L38429	L35062	L35000	L34519
	0184U	(A58017)	(A57332)	(A57141)	(A57100)	(A58917)	(A56199)	(A58918)
	0185U		L38351					
	0186U		(A57331)					
	0187U							
	0188U							
	0189U							
	0190U							
	0191U							
	0192U							
	0193U							
	0194U							
	0195U							
	0196U							
	0197U							
	0198U							
	0199U							
	0200U							
	0201U							
	0203U							
	0205U							
	0209U							
	0212U							
	0213U							
	0214U							
	0215U							
	0216U							
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	0221U							
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0236U								
0237U								
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0246U								

Molecular Diagnostic Genetic Tests Included in the Palmetto MoIDX Program

Accessed April 12, 2024

*Also refer to the [MACs with corresponding States/Territories](#).

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

Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Repeat Germline Testing	0258U	L38274	L38353	L38288	L38429	L35062	L35000	L34519
	0260U	(A58017)	(A57332)	(A57141)	(A57100)	(A58917)	(A56199)	(A58918)
	0264U		L38351					
	0265U		(A57331)					
	0266U							
	0267U							
	0268U							
	0269U							
	0270U							
	0271U							
	0272U							
	0273U							
	0274U							
	0276U							
	0277U							
	0278U							
	0282U							
	0286U							
	0289U							
	0290U							
	0291U							
	0292U							
	0293U							
	0294U							
	0318U							
	0345U							
	0347U							
	0348U							
	0349U							
	0350U							
	0355U							
	0378U							
	0380U							
0389U								
0392U								
0400U								
0401U								
0411U								
0417U								
0419U								
0425U								

Molecular Diagnostic Genetic Tests Included in the Palmetto MoIDX Program

Accessed April 12, 2024

* Also refer to the [MACs with corresponding States/Territories](#).

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

Test	Code	Palmetto MoIDX Program Guideline	LCDs/LCAs					First Coast
			Noridian	CGS	WPS	Novitas	NGS	
Repeat Germline Testing	0426U	L38274	L38353	L38288	L38429	L35062	L35000	L34519
	81479	(A58017)	(A57332) L38351 (A57331)	(A57141)	(A57100)	(A58917)	(A56199)	(A58918)
ResponseDx Tissue of Origin*	81504	L35025 (A53108)	L36256	L36021	L36807	L35062	L35000	L34519
			(A54496) L35160 (A54494)	(A54198)	(A55204)	(A58917)	(A56199)	(A58918)
RPS19 Gene Tests	81405	A53587	A55610	L36021	L36807	L35062	L35000	L34519
	81479		A55614 (A54299)	(A54299)	(A55205)	(A58917)	(A56199)	(A58918)
SEPT9 Gene Test	81327	A53702	A55623	L36021	L36807	L35062	L35000	L34519
			A55628 (A54300)	(A54300)	(A55206)	(A58917)	(A56199)	(A57451) (A58918)
SMPD1 Genetic Testing	81330	A53624	A55627	L36021	L36807	L35062	L35000	L34519
	81412		A55631 (A54285)	(A54285)	(A55208)	(A58917)	(A56199)	(A58918)
STAT3 Gene Testing	81405	A53562	A55480	L36021	L36807	L35062	L35000	L34519
			A55481 (A54284)	(A54284)	(A55209)	(A58917)	(A56199)	(A57451) (A58918)
SULT4A1 Genetic Testing	81479	A53538	A55596	L36021	L36807			
			A55601 (A54283)	(A54283)	(A55210)			
Targeted genomic sequence analysis panel, solid organ, or neoplasm	81455	L35025 (A56853)	L36256	L36021	L36807	L35062	L37810	L34519
			(A57527) L35160 (A57526)	(A56973)	(A57772)	(A58917)	(A56867)	(A58918)
TERC Gene Tests	81479	A53589	A55611	L36021	L36807			
			A55616 (A54282)	(A54282)	(A55211)			
TP53 Gene Test	81351	A53591	A55487	L36021	L36807	L35062	L35000	L34519
	81352		A55484 (A54281)	(A54281)	(A55221)	(A58917)	(A56199)	(A58918)
VEGFR2 Tests	81479	A53548	A55468	L36021	L36807			
			A55469 (A54279)	(A54279)	(A55232)			

Molecular Diagnostic Genetic Tests

Accessed March 4, 2024

* Also refer to the [MACs with corresponding States/Territories](#).

For states/territories with no LCDs/LCAs, refer to the applicable Palmetto MoIDX 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, MA, ME, 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

Molecular Diagnostic Genetic Tests

Accessed March 4, 2024

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

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	IA, IN, KS, MI, MO, NE

MyPRS™ Test for Multiple Myeloma Gene Expression Profile

Accessed November 20, 2023

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
04/10/2024	<p>Title Change</p> <ul style="list-style-type: none"> Previously titled <i>Genetic Testing</i> <p>Coverage Guidelines</p> <ul style="list-style-type: none"> Removed content/language addressing: <ul style="list-style-type: none"> Tumor markers Cytogenetic studies Next generation sequencing (NGS) Pharmacogenomic testing for warfarin response (CYP2C9 and VKORC1) (HCPCS code G9143 and CPT codes 81227 and 81355) Added language to indicate molecular pathology and molecular diagnostics are covered when Medicare coverage criteria are met Revised list of <i>Molecular Diagnostic Tests Included in the Palmetto MoIDX Program</i>: <ul style="list-style-type: none"> Added: <ul style="list-style-type: none"> Molecular biomarker testing to guide targeted therapy selection in rheumatoid arthritis Next-generation sequencing for solid tumors Next-generation sequencing lab-developed tests for myeloid malignancies and suspected myeloid malignancies Proteomics testing Removed: <ul style="list-style-type: none"> Cystatin C measurement FDA approved CLL companion diagnostic test Urine drug testing Updated descriptor/heading for: <ul style="list-style-type: none"> “4q25-AF risk genotype testing” (previously listed as “4q25-AF risk genotype coding”) “Minimal residual disease testing for cancer” (previously listed as “minimal residual disease testing for solid tumor”) “Targeted genomic sequence analysis panel, solid organ or neoplasm” (previously listed as “targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm”) <p>Supporting Information</p> <ul style="list-style-type: none"> Updated lists of applicable <i>Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs)</i> to reflect the most current information: <ul style="list-style-type: none"> Modified reference information for: <ul style="list-style-type: none"> 4kscore® assay

Date	Summary of Changes
	<ul style="list-style-type: none"> ▪ Abbott RealTime IDH1 and IDH2 testing for acute myeloid leukemia (AML) ▪ ABL1 gene analysis ▪ Afirma™ Assay by Veracyte ▪ Apoe genotype ▪ Aspartoacylase 2 deficiency (ASPA) testing ▪ ATP7B gene tests ▪ BCKDHB gene test ▪ BCR-ABL ▪ Negative myeloproliferative disease ▪ BDX-XL2 ▪ Biomarkers in cardiovascular risk assessment ▪ Lab: bladder/urothelial tumor markers ▪ BLM gene analysis ▪ Blood product molecular antigen typing ▪ Breast cancer assay: Prosigna ▪ Breast Cancer Index® (BCI) gene expression test ▪ CDH1 genetic testing ▪ CHD7 gene analysis ▪ EndoPredict breast cancer gene expression test ▪ FDA-approved BRAF tests ▪ FDA-approved EGFR tests ▪ FDA-approved KRAS tests ▪ GBA genetic testing ▪ Germline testing for use of PARP inhibitors ▪ GlycoMark® testing for glycemic control ▪ HBB gene test ▪ HLA testing for transplant histocompatibility ▪ Hypercoagulability/thrombophilia (Factor V Leiden, Factor II Prothrombin, and MTHFR) ▪ LKBKAP genetic testing ▪ Immunohistochemistry (IHC) indications for breast pathology ▪ Lab-developed tests for inherited cancer syndromes in patients with cancer ▪ MCOLN1 genetic testing ▪ Melanoma risk stratification molecular testing ▪ MGMT promoter methylation analysis ▪ Microsatellite instability-high (MSI-H) and mismatch repair deficient (DMMR) biomarker for patients with unresectable or metastatic solid tumors ▪ Minimal residual disease testing for cancer ▪ Molecular biomarkers to risk-stratify patients at increased risk for prostate cancer ▪ Molecular syndromic panels for infectious disease pathogen identification testing ▪ Molecular testing for detection of upper gastrointestinal metaplasia, dysplasia, and neoplasia ▪ Molecular testing for solid organ allograft rejection ▪ NRAS genetic testing ▪ PAX6 gene sequencing ▪ Percepta® bronchial genomic classifier ▪ Pharmacogenomics testing ▪ HLA testing for transplant histocompatibility ▪ Pigmented lesion assay ▪ PIK3CA gene tests ▪ Plasma-based genomic profiling in solid tumors ▪ Prognostic and predictive molecular classifiers for bladder cancer ▪ Promark® risk score ▪ Prometheus IBD SGI Diagnostic® policy ▪ Prostate cancer genomic classifier assay for men with localized disease

Date	Summary of Changes
	<ul style="list-style-type: none"> ▪ Repeat germline testing ▪ SEPT9 gene test ▪ STAT3 gene testing ▪ Targeted genomic sequence analysis panel, solid organ, or neoplasm <p>Administrative</p> <ul style="list-style-type: none"> • Archived previous policy version MCS040.11

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UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing the items or services in this coverage summary have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, UnitedHealthcare applies internal coverage criteria in the UnitedHealthcare commercial policies referenced in this coverage summary. The coverage criteria in these commercial policies was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

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