



August 17, 2018

Re: CMS Announces 6-Month Period of Enforcement Discretion for Laboratory Date of Service Exception Policy Under the Medicare Clinical Laboratory Fee Schedule (the "14 Day Rule")

Dear Valued Client:

As you may be aware, on July 3, 2018 the Centers for Medicare & Medicaid Services (CMS) announced that it is exercising enforcement discretion until January 2, 2019, with respect to the laboratory date of service (DOS) exception policy under the Medicare Clinical Laboratory Fee Schedule (CLFS) (See 42 CFR 414.510(b)(5)) (the "14 Day Rule"). This enforcement discretion applies to providers and suppliers with regard to advanced diagnostic laboratory tests (ADLTs) and molecular pathology tests subject to the new laboratory DOS exception policy, as adopted in the CY 2018 Medicare Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center final rule published on December 14, 2017 (See 82 FR 59393).

According to CMS, based on industry feedback that many providers and suppliers would not be able to implement the new laboratory DOS exception by the July 2, 2018 implementation date, CMS granted this extension to enable providers and suppliers additional time to develop the systems changes necessary to enable the performing laboratory to bill for tests subject to the new laboratory DOS exception. During the enforcement discretion period, hospitals may continue to bill for ADLTs and molecular pathology tests that would otherwise be subject to the new laboratory DOS exception, but does not prevent performing laboratories prepared to bill Medicare directly for ADLTs and molecular pathology tests subject to the new laboratory DOS exception from doing so before January 2, 2019. However, per CMS, in no case should both the hospital and the performing laboratory bill for the same test for the same beneficiary.

During this enforcement discretion period, NeoGenomics will be working with you to facilitate accurate implementation of the new laboratory DOS exception policy by January 2, 2019. To that end, and, to ensure that you have current information on the specific laboratory test codes subject to the laboratory DOS exception, please see the summary table attached as Exhibit A to this letter, which incorporates updated CPT codes published by Palmetto GBA, our Medicare contractor. You may also visit CMS' website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html>. Also, to ensure continued compliance with applicable coverage rules, effective August 1, 2018, NeoGenomics will no longer bill third party payers for code G0452, Molecular Interpretation.

If you have questions regarding this letter and the attachment, please contact your local Territory Business Manager for more information. Thank you for your continued assistance in complying with these updated Medicare changes.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Shovlin", is positioned above the typed name.

Robert J. Shovlin
President, Clinical Services

Attachment – Out-Patient Billing CPT Codes



Out-Patient Billing CPT Codes

Updated Date: August 13, 2018

Client Billed - Molecular Tests

Category	No.	Test Name	NeoGenomics Bills Client	NeoGenomics Bills Medicare
Other Panels & Profiles	1	HPV DNA Tissue Testing	87624	No

Medicare Billed - Molecular Tests

Category	No.	Test Name	NeoGenomics Bills Client	NeoGenomics Bills Medicare
NeoARRAY®	1	NeoARRAY SNP/Cytogenetic Profile	No	81229
NeoLAB™	2	NeoLAB AML Profile - Liquid Biopsy ¹	No	81450
	3	NeoLAB BTK Inhibitor Acquired Resistance Panel - Liquid Biopsy	No	81479
	4	NeoLAB EGFR T790M - Liquid Biopsy	No	81235
	5	NeoLAB FLT3 Mutation Analysis - Liquid Biopsy ²	No	81479
	6	NeoLAB IDH1 Mutation Analysis - Liquid Biopsy	No	81120
	7	NeoLAB IDH2 Mutation Analysis - Liquid Biopsy	No	81121
	8	NeoLAB inv(16), CBFβ-MYH11 Translocation - Liquid Biopsy	No	81401
	9	NeoLAB KIT (c-KIT) Mutation Analysis - Liquid Biopsy	No	81272
	10	NeoLAB KRAS Mutation Analysis - Liquid Biopsy ²	No	81275
	11	NeoLAB MDS/CMML Profile - Liquid Biopsy ¹	No	81450
	12	NeoLAB Myeloid Disorders Profile - Liquid Biopsy ¹	No	81455
	13	NeoLAB NPM1 Mutation Analysis - Liquid Biopsy	No	81310
	14	NeoLAB NRAS Mutation Analysis - Liquid Biopsy	No	81311
	15	NeoLAB PML-RARA Translocation, t(15;17) - Liquid Biopsy	No	81315
	16	NeoLAB Prostate - Liquid Biopsy	No	0011M
	17	NeoLAB RUNX1-RUNX1T1 (AML1-ETO) Translocation, t(8;21) - Liquid Biopsy	No	81401
	18	NeoLAB Solid Tumor Monitor - Liquid Biopsy	No	81479
	NeoTYPE®	19	NeoTYPE AML Prognostic Profile ¹	No
20		NeoTYPE AITL/Peripheral T-Cell Lymphoma Profile ¹	No	81479

¹ CPT Code G0452 is not billed in NeoTYPE, NeoLAB

² CPT code(s) updated - See "List of tests with updated CPT code(s)"

Note: Many NeoTYPE Profiles include FISH and IHC whose codes are not listed above and will be billed to the clients.

The CPT codes provided here are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed.

Medicare Billed - Molecular Tests (Continued)

Category	No.	Test Name	NeoGenomics Bills Client	NeoGenomics Bills Medicare
NeoTYPE®	21	NeoTYPE AML Favorable-Risk Profile ¹	No	81479
	22	NeoTYPE Brain Tumor Profile ^{1,2}	No	81479
	23	NeoTYPE Breast Tumor Profile ¹	No	81445
	24	NeoTYPE Cervical Tumor Profile ¹	No	81479
	25	NeoTYPE CLL Prognostic Profile ¹	No	81479
	26	NeoTYPE Colorectal Tumor Profile ¹	No	81445
	27	NeoTYPE Discovery Profile for Solid Tumors ¹	No	81455
	28	NeoTYPE Endometrial Tumor Profile ¹	No	81479
	29	NeoTYPE Esophageal Tumor Profile ¹	No	81445
	30	NeoTYPE Gastric Tumor Profile	No	81445
	31	NeoTYPE GI Predictive Profile ²	No	81479
	32	NeoTYPE GIST Profile ¹	No	81445
	33	NeoTYPE Head & Neck Tumor Profile ¹	No	81445
	34	NeoTYPE JMML Profile ¹	No	81450
	35	NeoTYPE Liposarcoma Fusion Profile ¹	No	81479
	36	NeoTYPE Liver/Biliary Tumor Profile ¹	No	81479
	37	NeoTYPE Lung Tumor Profile ¹	No	81445
	38	NeoTYPE Lymphoma Profile ¹	No	81450
	39	NeoTYPE MDS/CMML Profile ¹	No	81450
	40	NeoTYPE Melanoma Profile ¹	No	81445
	41	NeoTYPE MPN Profile ¹	No	81450
	42	NeoTYPE Myeloid Disorders Profile ¹	No	81455
	43	NeoTYPE Other Solid Tumor Profile ¹	No	81479
	44	NeoTYPE Ovarian Tumor Profile ¹	No	81445
	45	NeoTYPE Pancreas Tumor Profile ¹	No	81445
	46	NeoTYPE Precision Profile for Solid Tumors ¹	No	81445
	47	NeoTYPE Soft Tissue Tumor Profile ¹	No	81479
	48	NeoTYPE Thyroid Profile ¹	No	81445
Other Panels & Profiles	49	BRCA1 Mutation & Del/Dup Analysis	No	81214
	50	BRCA1/2 Mutation & Del/Dup Analysis	No	81162
	51	Hereditary Cancer Comprehensive Panel	No	81432
	52	Hereditary Cancer Susceptibility for Pediatrics	No	81450
	53	Hereditary DNA Repair Panel for Prostate Cancer	No	81445

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Medicare Billed - Molecular Tests (Continued)

Category	No.	Test Name	NeoGenomics Bills Client	NeoGenomics Bills Medicare
Other Panels & Profiles	54	Lynch Syndrome	No	81445
	55	ABL1 Kinase Domain Mutation Analysis	No	81170
	56	ALK Mutation Analysis	No	81479
	57	Androgen Receptor Mutation Analysis	No	81405
	58	ASXL1 Mutation Analysis	No	81175
	59	ATRX Mutation Analysis	No	81479
	60	B-Cell Gene Rearrangement ²	No	81479
	61	BCL1 Translocation, t(11;14)	No	81401
	62	BCL2 Translocation, t(14;18) ²	No	81401
	63	BCR-ABL1 Non-Standard p230	No	81208
	64	BCR-ABL1 Standard p210, p190 ²	No	81479
	65	BRAF Mutation Analysis	No	81210
	66	BRCA2 Mutation & Del/Dup Analysis	No	81216
	67	BTK Inhibitor Acquired Resistance Panel	No	81479
	68	BTK Inhibitor Primary Susceptibility Panel	No	81479
	69	BTK Mutation Analysis ²	No	81406
	70	CALR Mutation Analysis	No	81219
	71	CARD11 Mutation Analysis	No	81479
	72	CBL Mutation Analysis	No	81479
	73	CD79B Mutation Analysis	No	81479
	74	CEBPA Mutation Analysis	No	81218
	75	Chimerism/DNA Fingerprinting Analysis	No	81265 or 81266 or 81267 or 81268
	76	CSF3R Mutation Analysis	No	81479
	77	CXCR4 Mutation Analysis	No	81479
	78	DNMT3A Mutation Analysis	No	81403
	79	EGFR Mutation Analysis	No	81235
	80	EGFR T790M Germline Mutation Analysis	No	81235
	81	EGFRvIII Analysis	No	81479
	82	EPCAM Mutation & Del/Dup Analysis	No	81403
	83	ETV6 Mutation Analysis	No	81479
	84	ETV6-RUNX1 (TEL-AML1) Translocation, t(12;21)	No	81401
	85	EZH2 Mutation Analysis	No	81479

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Medicare Billed - Molecular Tests (Continued)

Category	No.	Test Name	NeoGenomics Bills Client	NeoGenomics Bills Medicare
Other Panels & Profiles	86	FLT3 Mutation Analysis ²	No	81479
	87	GNAS Mutation Analysis	No	81479
	88	HOXB13 Genotyping	No	81479
	89	HRAS Mutation Analysis	No	81403
	90	HSD3B1 Genotyping	No	81479
	91	IDH1 & IDH2 Mutation Analysis ²	No	81479
	92	IgH Clonality/MRD by NGS	No	81263
	93	IgVH Mutation Analysis	No	81263
	94	Inherited Bone Marrow Failure Panel ²	No	81450
	95	inv(16), CBFβ-MYH11 Translocation	No	81401
	96	JAK2 Exon 12-14 Mutation Analysis	No	JAK2 Exon 12-14 only: 81403x1. JAK2 V617F and Exon 12-14 run concurrently or by reflex: 81270x1, 81403x1
	97	JAK2 V617F Mutation Analysis	No	JAK2 V617F only: 81270x1. JAK2 V617F and Exon 12-14 run concurrently or by reflex: 81270x1, 81403x1
	98	KIT (c-KIT) Mutation Analysis	No	81272
	99	KRAS Exon 4 Mutation Analysis	No	81276
	100	KRAS Mutation Analysis ²	No	81275
	101	MET (c-MET) Mutation Analysis	No	81479
	102	MET Exon 14 Deletion Analysis	No	81479
	103	MGMT Promoter Methylation Analysis	No	81287
	104	Microsatellite Instability Analysis (MSI)	No	81301
	105	MLH1 Mutation & Del/Dup Analysis	No	81294
	106	MLH1 Promoter Methylation Analysis	No	81288
107	MPL Mutation Analysis	No	81402	
108	MPN Extended Reflex Panel ²	No	81479	
109	MPN Standard Reflex Panel ²	No	81270	
110	MSH2 Mutation & Del/Dup Analysis	No	81297	
111	MSH6 Mutation & Del/Dup Analysis	No	81298	

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Medicare Billed - Molecular Tests (Continued)

Category	No.	Test Name	NeoGenomics Bills Client	NeoGenomics Bills Medicare
Other Panels & Profiles	112	MYD88 Mutation Analysis	No	81479
	113	NGS ALK, NTRK, RET, ROS1 Fusion Profile ²	No	81479
	114	NGS ALK, RET, ROS1 Fusion Profile ²	No	81479
	115	NGS Comprehensive Sarcoma Fusion Profile ²	No	81479
	116	NGS Ewing Sarcoma Fusion Profile	No	81479
	117	NGS Non-Ewing Sarcoma Fusion Profile ²	No	81479
	118	NGS Pediatric Sarcoma Fusion Profile ²	No	81479
	119	NGS Rhabdomyosarcoma Fusion Profile	No	81479
	120	NGS Thyroid Fusion Profile ²	No	81479
	121	NOTCH1 Mutation Analysis	No	81407
	122	NPM1 MRD Mutation Analysis	No	81310
	123	NPM1 Mutation Analysis	No	81310
	124	NRAS Exon 4 Mutation Analysis	No	81403
	125	NRAS Mutation Analysis	No	81311
	126	OncoPrint™ Dx Target Test	No	0022U
	127	PDGFRa Mutation Analysis	No	81314
	128	PIK3CA Mutation Analysis	No	81404
	129	PLC-Gamma-2 Mutation Analysis	No	81479
	130	PML-RARA Translocation, t(15;17)	No	81315
	131	PMS2 Mutation & Del/Dup Analysis	No	81317
	132	PPM1D Mutation Analysis	No	81479
	133	PTEN Mutation Analysis	No	81321
	134	PTPN11 Mutation Analysis	No	81406
	135	RAS/RAF Panel ²	No	81479
	136	RHOA Mutation Analysis	No	81479
	137	RUNX1 Mutation Analysis ²	No	81334
	138	RUNX1-RUNX1T1 (AML1-ETO) Translocation, t(8;21)	No	81401
	139	SETBP1 Mutation Analysis	No	81479
	140	SF3B1 Mutation Analysis	No	81479
	141	SRSF2 Mutation Analysis	No	81479
142	STAT3 Mutation Analysis	No	81405	
143	T-Cell Receptor Beta Gene Rearrangement	No	81340	
144	T-Cell Receptor Gamma Gene Rearrangement	No	81342	

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Medicare Billed - Molecular Tests (Continued)

Category	No.	Test Name	NeoGenomics Bills Client	NeoGenomics Bills Medicare
Other Panels & Profiles	145	TERT Promoter Mutation Analysis	No	81479
	146	TET2 Mutation Analysis	No	81479
	147	TP53 Mutation Analysis	No	81405
	148	TPMT Genotyping	No	81335
	149	Tumor Mutation Burden	No	81479
	150	U2AF1 Mutation Analysis	No	81479
	151	UGT1A1 Genotyping	No	81350
	152	Universal Fusion/Expression Profile ²	No	81450
	153	WT1 Mutation Analysis ²	No	81405
	154	ZRSR2 Mutation Analysis	No	81479

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List of Tests with Updated CPT Code(s)

Test No.	Test Name	March 2018		August 2018	
		NeoGenomics Bills Client	NeoGenomics Bills Medicare	NeoGenomics Bills Client	NeoGenomics Bills Medicare
5	NeoLAB FLT3 Mutation Analysis - Liquid Biopsy	No	81245, 81246	No	81479
10	NeoLAB KRAS Mutation Analysis - Liquid Biopsy	No	81275, 81276	No	81275
22	NeoTYPE Brain Tumor Profile	No	81445, G0452	No	81479
31	NeoTYPE GI Predictive Profile	No	81210, 81403x2, 81275, 81276x2, 81311, 81301, G0452	No	81479
60	B-Cell Gene Rearrangement	No	81261, 81264	No	81479
62	BCL2 Translocation, t(14;18)	No	81402	No	81401
64	BCR-ABL1 Standard p210, p190	No	81206, 81207	No	81479
69	BTK Mutation Analysis	No	81479	No	81406
86	FLT3 Mutation Analysis	No	81245	No	81479
91	IDH1 & IDH2 Mutation Analysis	No	81120, 81121	No	81479
94	Inherited Bone Marrow Failure Panel	No	81455, 81479	No	81450
100	KRAS Mutation Analysis	No	81275, 81276	No	81275

List of Tests with Updated CPT Code(s) (Continued)

Test No.	Test Name	March 2018		August 2018	
		NeoGenomics Bills Client	NeoGenomics Bills Medicare	NeoGenomics Bills Client	NeoGenomics Bills Medicare
108	MPN Extended Reflex Panel	No	81219, 81270, 81402, 81403	No	81479
109	MPN Standard Reflex Panel	No	81270, 81402, 81403	No	81270
113	NGS ALK, NTRK, RET, ROS1 Fusion Profile	No	81445	No	81479
114	NGS ALK, RET, ROS1 Fusion Profile	No	81404, 81479x2	No	81479
115	NGS Comprehensive Sarcoma Fusion Profile	No	81445	No	81479
117	NGS Non-Ewing Sarcoma Fusion Profile	No	81445	No	81479
118	NGS Pediatric Sarcoma Fusion Profile	No	81445	No	81479
120	NGS Thyroid Fusion Profile	No	81405, 81479x2	No	81479
135	RAS/RAF Panel	No	81311x1, 81404x1, 81405x1, 81406x1	No	81479
137	RUNX1 Mutation Analysis	No	81401	No	81334
152	Universal Fusion/Expression Profile	No	81455	No	81450



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