Local Coverage Article:
Billing and Coding: MolDX: Testing of Multiple Genes (A57503)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Palmetto GBA	A and B MAC	10111 - MAC A	J - J	Alabama
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10211 - MAC A	J - J	Georgia
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10311 - MAC A	J - J	Tennessee
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11201 - MAC A	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11301 - MAC A	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11401 - MAC A	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11501 - MAC A	J - M	North Carolina
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

Article Information

General Information

Article ID
A57503

Article Title
Billing and Coding: MolDX: Testing of Multiple Genes

Article Type
Billing and Coding

AMA CPT / ADA CDT / AHA NUBC Copyright Statement
CPT codes, descriptions and other data only are

Original Effective Date
10/21/2019

Revision Effective Date
01/01/2020

Revision Ending Date
N/A

Retirement Date
N/A

CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A) allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

Title 42 CFR §410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions

Article Guidance

Article Text:

The following information will be effective 10/21/2019 for dates of service on or after 10/15/2019.

A panel of genes is a distinct procedural service from a series of individual genes. All services billed to Medicare must be reasonable and necessary. As such, if a provider or supplier submits a claim for a panel, then the patient's medical record must reflect that the panel was reasonable and necessary. Alternatively, if a provider or supplier bills for a number of individual genes, then the patient's medical record must reflect that each individual gene is reasonable and necessary.

For ease of reading the term "gene" when used in this document will be used to indicate a gene, region of a gene, and / or variant(s) of a gene.

Genes can be assayed serially or in parallel. Genes assayed on the same date of service are considered to be assayed in parallel if the result of one assay does not affect the decision to complete the assay on another gene, and the two genes are being tested for the same indication. Genes assayed on the same date of service are considered to be assayed serially when there is a reflexive decision component where the results of the analysis of one or more genes determines whether the results of additional analyses are reasonable and necessary.

If a laboratory assays two or more genes in a patient in parallel, then those two or more genes will be considered part of the same panel. A panel constitutes a single procedural service, so one HCPCS codes must be submitted for the panel. If the laboratory assays genes in serial, then the laboratory must submit claims for genes individually. The order by the treating clinician must reflect whether the treating clinician is ordering a panel or single genes, and additionally, the patient's medical record must reflect that the service billed was reasonable and necessary.

Two examples:

Single Service Example: A clinician orders 5 specific genes associated with breast cancer. The laboratory analyzes the 5 genes for common mutations using polymerase chain reaction. All 5 PCR procedures are started prior to the results of any one PCR procedure being known. The results are signed off on simultaneously, and all 5 results are sent to a clinician.

This would be considered a single procedural service, a single 5 gene panel, and it must be billed as such. This single panel must be reasonable and necessary to be billed to Medicare.

Multiple Distinct Procedural Services Example: A clinician requests that genes associated with early onset colorectal cancer be analyzed in a patient. The clinician orders stepwise reflex testing where a negative or positive result in one gene determines whether additional analysis on other genes will be performed or what that will be.

Each gene assayed represents one procedural service, so if more than one gene is analyzed, then multiple procedural services may be billed in some patients for whom reflex testing goes beyond the first gene. Each gene billed to Medicare must be individually reasonable and necessary. A clinician's order is not by itself sufficient to indicate that a test was reasonable and necessary. The record must reflect that the test is used in the management of the beneficiary's specific medical problem in accordance with CFR §410.32.

Labs must register a test with the Diagnostics Exchange as it reflected on the order form and is run in the laboratory. If a gene / variant is tested as part of a panel, then the lab must register the panel and must submit the correct z-code and CPT code for the panel. If a lab has a panel but sometimes also analyzes individual genes from the panel, the lab must register both the panel and the individual genes that are analyzed.

In general two or more codes describing a genetic test billed on the same beneficiary on the same date may constitute a panel, and if so the service must be billed as a single procedural service. We would generally expect that

a provider or supplier would not bill for more than two distinct laboratory genetic testing procedural services on a single beneficiary on a single date of service. If providers or suppliers do bill for more than two distinct laboratory genetic testing procedural services on a single beneficiary on a single date of service, the provider or supplier must attest that each additional service billed is a distinct procedural service using the 59 modifier.

The use of the 59 modifier will be considered an attestation that distinct procedural services are being performed rather than a panel. Providers and suppliers must use the 59 modifier in conjunction with other modifiers where appropriate. When providers and suppliers bill for multiple distinct procedural services, each service must be reasonable and necessary.

Laboratories that are billing for many individual genes using the 59 modifier rather than panels may be subject to medical review as outliers.

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

When more than two codes from this list are submitted for the same beneficiary on the same date of service, the claims processing system will reject every code submitted after the first two services. However, if a lab runs more than two distinct procedural services from this list on a single date of service, then the lab must use the 59 modifier with each additional service billed as an attestation that it is a distinct procedural service.

Group 1 Codes:

CODE	DESCRIPTION
81120	Idh1 common variants
81121	Idh2 common variants
81161	Dmd dup/delet analysis
81162	Brca1&2 gen full seq dup/del
81163	Brca1&2 gene full seq alys
81164	Brca1&2 gen ful dup/del alys
81165	Brca1 gene full seq alys
81166	Brca1 gene full dup/del alys
81167	Brca2 gene full dup/del alys
81170	Abl1 gene
81171	Aff2 gene detc abnor alleles
81172	Aff2 gene charac alleles
81173	Ar gene full gene sequence

CODE	DESCRIPTION
81174	Ar gene known famil variant
81175	Asxl1 full gene sequence
81176	Asxl1 gene target seq alys
81177	Atn1 gene detc abnor alleles
81178	Atxn1 gene detc abnor allele
81179	Atxn2 gene detc abnor allele
81180	Atxn3 gene detc abnor allele
81181	Atxn7 gene detc abnor allele
81182	Atxn8os gen detc abnor allel
81183	Atxn10 gene detc abnor allel
81184	Cacna1a gen detc abnor allel
81185	Cacna1a gene full gene seq
81186	Cacna1a gen known famil vrnt
81187	Cnbp gene detc abnor allele
81188	Cstb gene detc abnor allele
81189	Cstb gene full gene sequence
81190	Cstb gene known famil vrnt
81200	Aspa gene
81201	Apc gene full sequence
81202	Apc gene known fam variants
81203	Apc gene dup/delet variants
81204	Ar gene charac alleles
81205	Bckdhb gene
81206	Bcr/abl1 gene major bp
81207	Bcr/abl1 gene minor bp
81208	Bcr/abl1 gene other bp
81209	Blm gene
81210	Braf gene
81212	Brca1&2 185&5385&6174 vrnt
81215	Brca1 gene known famil vrnt
81216	Brca2 gene full seq alys
81217	Brca2 gene known famil vrnt

CODE	DESCRIPTION
81218	Cebpa gene full sequence
81219	Calr gene com variants
81220	Cftr gene com variants
81221	Cftr gene known fam variants
81222	Cftr gene dup/delet variants
81223	Cftr gene full sequence
81224	Cftr gene intron poly t
81225	Cyp2c19 gene com variants
81226	Cyp2d6 gene com variants
81227	Cyp2c9 gene com variants
81228	Cytogen micrarray copy nmbr
81229	Cytogen m array copy no&snp
81230	Cyp3a4 gene common variants
81231	Cyp3a5 gene common variants
81232	Dpyd gene common variants
81233	Btk gene common variants
81234	Dmpk gene detc abnor allele
81235	Egfr gene com variants
81236	Ezh2 gene full gene sequence
81237	Ezh2 gene common variants
81238	F9 full gene sequence
81239	Dmpk gene charac alleles
81240	F2 gene
81241	F5 gene
81242	Fancc gene
81243	Fmr1 gene detection
81244	Fmr1 gene charac alleles
81245	Flt3 gene
81246	Flt3 gene analysis
81247	G6pd gene alys cmn variant
81248	G6pd known familial variant
81249	G6pd full gene sequence

CODE	DESCRIPTION
81250	G6pc gene
81251	Gba gene
81252	Gjb2 gene full sequence
81253	Gjb2 gene known fam variants
81254	Gjb6 gene com variants
81255	Hexa gene
81256	Hfe gene
81257	Hba1/hba2 gene
81258	Hba1/hba2 gene fam vrnt
81259	Hba1/hba2 full gene sequence
81260	Ikbkap gene
81261	Igh gene rearrange amp meth
81262	Igh gene rearrang dir probe
81263	Igh vari regional mutation
81264	Igk rearrangeabn clonal pop
81265	Str markers specimen anal
81266	Str markers spec anal addl
81267	Chimerism anal no cell selec
81268	Chimerism anal w/cell select
81269	Hba1/hba2 gene dup/del vrnts
81270	Jak2 gene
81271	Htt gene detc abnor alleles
81272	Kit gene targeted seq analys
81273	Kit gene analys d816 variant
CODE	DESCRIPTION
81274	Htt gene charac alleles
81275	Kras gene variants exon 2
81276	Kras gene addl variants
81283	Ifnl3 gene
81284	Fxn gene detc abnor alleles
81285	Fxn gene charac alleles
81286	Fxn gene full gene sequence

CODE	DESCRIPTION
81287	Mgmt gene prmtr mthyltn alys
81288	Mlh1 gene
81289	Fxn gene known famil variant
81290	Mcoln1 gene
81291	Mthfr gene
81292	Mlh1 gene full seq
81293	Mlh1 gene known variants
81294	Mlh1 gene dup/delete variant
81295	Msh2 gene full seq
81296	Msh2 gene known variants
81297	Msh2 gene dup/delete variant
81298	Msh6 gene full seq
81299	Msh6 gene known variants
81300	Msh6 gene dup/delete variant
81301	Microsatellite instability
81302	Mecp2 gene full seq
81303	Mecp2 gene known variant
81304	Mecp2 gene dup/delet variant
81305	Myd88 gene p.leu265pro vrnt
81306	Nudt15 gene common variants
81307	Palb2 gene full gene seq
81308	Palb2 gene known famil vrnt
81309	Pik3ca gene trgt seq alys
81310	Npm1 gene
81311	Nras gene variants exon 2&3
81312	Pabpn1 gene detc abnor allel
81313	Pca3/klk3 antigen
81314	Pdgfra gene
81315	Pml/raralpha com breakpoints
81316	Pml/raralpha 1 breakpoint
81317	Pms2 gene full seq analysis
81318	Pms2 known familial variants

CODE	DESCRIPTION
81319	Pms2 gene dup/delet variants
81320	Plcg2 gene common variants
81321	Pten gene full sequence
81322	Pten gene known fam variant
81323	Pten gene dup/delet variant
81324	Pmp22 gene dup/delet
81325	Pmp22 gene full sequence
81326	Pmp22 gene known fam variant
81327	Sept9 gen prmtr mthyltn alys
81328	Slco1b1 gene com variants
81329	Smn1 gene dos/deletion alys
81330	Smpd1 gene common variants
81331	Snrpn/ube3a gene
81332	Serpina1 gene
81333	Tgfbi gene common variants
81334	Runx1 gene targeted seq alys
81335	Tpmt gene com variants
81336	Smn1 gene full gene sequence
81337	Smn1 gen nown famil seq vrnt
81340	Trb@ gene rearrange amplify
81341	Trb@ gene rearrange dirprobe
81342	Trg gene rearrangement anal
81343	Ppp2r2b gen detc abnor allel
81344	Tbp gene detc abnor alleles
81345	Tert gene targeted seq alys
81346	Tyms gene com variants
81350	Ugt1a1 gene common variants
81355	Vkorc1 gene
81361	Hbb gene com variants
81362	Hbb gene known fam variant
81363	Hbb gene dup/del variants
81364	Hbb full gene sequence

CODE	DESCRIPTION
81370	Hla i & ii typing lr
81371	Hla i & ii type verify lr
81372	Hla i typing complete lr
81373	Hla i typing 1 locus lr
81374	Hla i typing 1 antigen lr
81375	Hla ii typing ag equiv lr
81376	Hla ii typing 1 locus lr
81377	Hla ii type 1 ag equiv lr
81378	Hla i & ii typing hr
81379	Hla i typing complete hr
81380	Hla i typing 1 locus hr
81381	Hla i typing 1 allele hr
81382	Hla ii typing 1 loc hr
81383	Hla ii typing 1 allele hr
81400	Mopath procedure level 1
81401	Mopath procedure level 2
81402	Mopath procedure level 3
81403	Mopath procedure level 4
81404	Mopath procedure level 5
81405	Mopath procedure level 6
81406	Mopath procedure level 7
81407	Mopath procedure level 8
81408	Mopath procedure level 9

Group 2 Paragraph:

If any code on this list is billed on a given date of service, then no other code from either this list or list 1 above should also be billed on that date of service, unless it represents a distinct procedural service. If so, providers and suppliers must append the 59 modifier as an attestation that the additional services are separately payable service.

Group 2 Codes:

CODE	DESCRIPTION
81410	Aortic dysfunction/dilation
81411	Aortic dysfunction/dilation

CODE	DESCRIPTION
81412	Ashkenazi jewish assoc dis
81413	Car ion chnnlpath inc 10 gns
81414	Car ion chnnlpath inc 2 gns
81430	Hearing loss sequence analys
81431	Hearing loss dup/del analys
81432	Hrdtry brst ca-rlatd dsordrs
81433	Hrdtry brst ca-rlatd dsordrs
81434	Hereditary retinal disorders
81435	Hereditary colon ca dsordrs
81436	Hereditary colon ca dsordrs
81437	Heredtry nurondcrn tum dsrdr
81438	Heredtry nurondcrn tum dsrdr
81439	Hrdtry cardmypy gene panel
81440	Mitochondrial gene
81442	Noonan spectrum disorders
81443	Genetic tstg severe inh cond
81445	Targeted genomic seq analys
81448	Hrdtry perph neurphy panel
81450	Targeted genomic seq analys

CPT/HCPCS Modifiers

Group 1 Paragraph:

N/A

Group 1 Codes:

CODE	DESCRIPTION
59	DISTINCT PROCEDURAL SERVICE: UNDER CERTAIN CIRCUMSTANCES, THE PHYSICIAN MAY NEED TO INDICATE THAT A PROCEDURE OR SERVICE WAS DISTINCT OR INDEPENDENT FROM OTHER SERVICES PERFORMED ON THE SAME DAY. MODIFIER -59 IS USED TO IDENTIFY PROCEDURES/SERVICES THAT ARE NOT NORMALLY REPORTED TOGETHER, BUT ARE APPROPRIATE UNDER THE CIRCUMSTANCES. THIS MAY REPRESENT A DIFFERENT SESSION OR PATIENT ENCOUNTER, DIFFERENT PROCEDURE OR SURGERY, DIFFERNET SITE OR ORGAN SYSTEM, SEPARATE INCISION/EXCISION, SEPARATE LESION, OR SEPARATE INJURY (OR AREA OF INJURY IN EXTENSIVE INJURIES) NOT ORDINARILY ENCOUNTERED

CODE	DESCRIPTION
	OR PERFORMED ON THE SAME DAY BY THE SAME PHYSICIAN. HOWEVER, WHAN ANOTHER ALREADY ESTABLISHED MODIFIER IS APPROPRIATE IT SHOULD BE USED RATHER THAN MODIFIER -59. ONLY IF NO MORE DESCRIPTIVE MODIFIER IS AVAILABLE, AND THE USE OF MODIFIER -59 BEST EXPLAINS THE CIRCUMSTANCES, SHOULD MODIFIER -59 BE USED. MODIFIER CODE 09959 MAY BE USED AS AN ALTERNATE TO MODIFIER -59.

Group 2 Paragraph:

N/A

Group 2 Codes:

CODE	DESCRIPTION
59	DISTINCT PROCEDURAL SERVICE: UNDER CERTAIN CIRCUMSTANCES, THE PHYSICIAN MAY NEED TO INDICATE THAT A PROCEDURE OR SERVICE WAS DISTINCT OR INDEPENDENT FROM OTHER SERVICES PERFORMED ON THE SAME DAY. MODIFIER -59 IS USED TO IDENTIFY PROCEDURES/SERVICES THAT ARE NOT NORMALLY REPORTED TOGETHER, BUT ARE APPROPRIATE UNDER THE CIRCUMSTANCES. THIS MAY REPRESENT A DIFFERENT SESSION OR PATIENT ENCOUNTER, DIFFERENT PROCEDURE OR SURGERY, DIFFERNET SITE OR ORGAN SYSTEM, SEPARATE INCISION/EXCISION, SEPARATE LESION, OR SEPARATE INJURY (OR AREA OF INJURY IN EXTENSIVE INJURIES) NOT ORDINARILY ENCOUNTERED OR PERFORMED ON THE SAME DAY BY THE SAME PHYSICIAN. HOWEVER, WHAN ANOTHER ALREADY ESTABLISHED MODIFIER IS APPROPRIATE IT SHOULD BE USED RATHER THAN MODIFIER -59. ONLY IF NO MORE DESCRIPTIVE MODIFIER IS AVAILABLE, AND THE USE OF MODIFIER -59 BEST EXPLAINS THE CIRCUMSTANCES, SHOULD MODIFIER -59 BE USED. MODIFIER CODE 09959 MAY BE USED AS AN ALTERNATE TO MODIFIER -59.

ICD-10 Codes that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

N/A

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type.Complete absence of all

Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

Other Coding Information

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2020	R1	Under **CPT/HCPCS Codes Group 1: Codes** added CPT® codes 81307, 81308, and 81309. The code description was revised for CPT® code 81350. This revision is due to the Annual CPT®/HCPCS Code Update and becomes effective on 1/1/2020.

Associated Documents

Related Local Coverage Document(s)

N/A

Related National Coverage Document(s)

N/A

Statutory Requirements URL(s)

N/A

Rules and Regulations URL(s)

N/A

CMS Manual Explanations URL(s)

N/A

Other URL(s)

N/A

Public Version(s)

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