

Is Your Lab Billing Medicare Directly for Advanced Diagnostic Lab Tests & Molecular Pathology Tests?

Background

In December 2017, the Centers for Medicare and Medicaid (CMS) published Change Request 10419, Transmittal 4000 that finalized an exception to its current laboratory DOS policy for Advanced Diagnostic Laboratory Tests (ADLTs) and molecular pathology tests excluded from the Outpatient Prospective Payment System (OPPS). Within the conditions specified below, the exception required that the DOS for those particular tests would be the date the test was performed, not the date the specimen was obtained.

1. The test was performed following a hospital outpatient's discharge from the hospital outpatient department;
2. The specimen was collected from a hospital outpatient during an encounter;
3. It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;
4. The results of the test do not guide treatment provided during the hospital outpatient encounter; and
5. The test was reasonable and medically necessary for the treatment of an illness.

This DOS exception essentially unbundled payment for the performance of these tests from the hospital's payment, allowing the performing lab to bill Medicare and be reimbursed for those tests directly. The exception was effective January 1, 2018, with a required implementation date of July 2, 2018.

On July 3, 2018, due to feedback from providers and suppliers who couldn't accommodate the DOS exception policy by the July 2, 2018 deadline, CMS announced it would exercise enforcement discretion which allowed an additional six months for performing labs to complete the necessary system changes to come into compliance with the policy.

On December 26, 2018, CMS announced it would extend the enforcement discretion period for an additional six months due to the number of entities who were still not able to implement the necessary system modifications by the January 2, 2019, deadline.

What do you need to do?

CMS directs that "during the enforcement discretion period, labs that are prepared to bill Medicare directly for the ADLTs and molecular pathology tests subject to the laboratory DOS exception should do so and those that are not ready should make every effort to comply with the requirements as soon as possible. We remind hospitals and performing laboratories that in no case should both the hospital and the performing laboratory bill for the same test for the same beneficiary."

For additional information on the laboratory DOS exception policy and FAQ's, visit:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html>



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The list of laboratory tests subject to the DOS exception as of January 1, 2019, follows:

Medicare Clinical Laboratory Fee Schedule		
Revised Laboratory Date of Service (DOS) Policy		
Laboratory Tests For Which the DOS is the Date the Test is Performed		
Revisions to Previous Lists Indicated By Bolded Font		
HCPCS Code	Short Descriptor	Effective Date
81105	Hpa-1 genotyping	1/1/2018
81106	Hpa-2 genotyping	1/1/2018
81107	Hpa-3 genotyping	1/1/2018
81108	Hpa-4 genotyping	1/1/2018
81109	Hpa-5 genotyping	1/1/2018
81110	Hpa-6 genotyping	1/1/2018
81111	Hpa-9 genotyping	1/1/2018
81112	Hpa-15 genotyping	1/1/2018
81120	ldh1 common variants	1/1/2018
81121	ldh2 common variants	1/1/2018
81161	Dmd dup/delet analysis	1/1/2018
81162	Brca1&2 seq & full dup/del	1/1/2018
81170	Abl1 gene	1/1/2018
81175	Asxl1 full gene sequence	1/1/2018
81176	Asxl1 gene target seq alys	1/1/2018
81200	Aspa gene	1/1/2018
81201	Apc gene full sequence	1/1/2018
81202	Apc gene known fam variants	1/1/2018
81203	Apc gene dup/delet variants	1/1/2018
81205	Bckdhb gene	1/1/2018
81206	Bcr/abl1 gene major bp	1/1/2018
81207	Bcr/abl1 gene minor bp	1/1/2018
81208	Bcr/abl1 gene other bp	1/1/2018
81209	Blm gene	1/1/2018
81210	Braf gene	1/1/2018
81211	Brca1&2 seq & com dup/del	Code deleted by the AMA on 12/31/2018
81212	Brca1&2 185&5385&6174 var	1/1/2018



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81213	Brca1&2 uncom dup/del var	Code deleted by the AMA on 12/31/2018
81214	Brca1 full seq & com dup/del	Code deleted by the AMA on 12/31/2018
81215	Brca1 gene known fam variant	1/1/2018
81216	Brca2 gene full sequence	1/1/2018
81217	Brca2 gene known fam variant	1/1/2018
81218	Cebpa gene full sequence	1/1/2018
81219	Calr gene com variants	1/1/2018
81220	Cftr gene com variants	1/1/2018
81221	Cftr gene known fam variants	1/1/2018
81222	Cftr gene dup/delet variants	1/1/2018
81223	Cftr gene full sequence	1/1/2018
81224	Cftr gene intron poly t	1/1/2018
81225	Cyp2c19 gene com variants	1/1/2018
81226	Cyp2d6 gene com variants	1/1/2018
81227	Cyp2c9 gene com variants	1/1/2018
81228	Cytogen micrarray copy nmb	1/1/2018
81229	Cytogen m array copy no&sn	1/1/2018
81230	Cyp3a4 gene common variants	1/1/2018
81231	Cyp3a5 gene common variants	1/1/2018
81232	Dpyd gene common variants	1/1/2018
81235	Egfr gene com variants	1/1/2018
81238	F9 full gene sequence	1/1/2018
81240	F2 gene	1/1/2018
81241	F5 gene	1/1/2018
81242	Fancc gene	1/1/2018
81243	Fmr1 gene detection	1/1/2018
81244	Fmr1 gene characterization	1/1/2018
81245	Flt3 gene	1/1/2018
81246	Flt3 gene analysis	1/1/2018
81247	G6pd gene alys cmn variant	1/1/2018
81248	G6pd known familial variant	1/1/2018
81249	G6pd full gene sequence	1/1/2018
81250	G6pc gene	1/1/2018
81251	Gba gene	1/1/2018



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81252	Gjb2 gene full sequence	1/1/2018
81253	Gjb2 gene known fam variants	1/1/2018
81254	Gjb6 gene com variants	1/1/2018
81255	Hexa gene	1/1/2018
81256	Hfe gene	1/1/2018
81257	Hba1/hba2 gene	1/1/2018
81258	Hba1/hba2 gene fam vrnt	1/1/2018
81259	Hba1/hba2 full gene sequence	1/1/2018
81260	lkbkap gene	1/1/2018
81261	Igh gene rearrange amp meth	1/1/2018
81262	Igh gene rearrang dir probe	1/1/2018
81263	Igh vari regional mutation	1/1/2018
81264	Igk rearrangeabn clonal pop	1/1/2018
81265	Str markers specimen anal	1/1/2018
81266	Str markers spec anal addl	1/1/2018
81267	Chimerism anal no cell selec	1/1/2018
81268	Chimerism anal w/cell select	1/1/2018
81269	Hba1/hba2 gene dup/del vrnts	1/1/2018
81270	Jak2 gene	1/1/2018
81272	Kit gene targeted seq analys	1/1/2018
81273	Kit gene analys d816 variant	1/1/2018
81275	Kras gene variants exon 2	1/1/2018
81276	Kras gene addl variants	1/1/2018
81283	Ifnl3 gene	1/1/2018
81287	Mgmt gene methylation anal	1/1/2018
81288	Mlh1 gene	1/1/2018
81290	Mcoln1 gene	1/1/2018
81291	Mthfr gene	1/1/2018
81292	Mlh1 gene full seq	1/1/2018
81293	Mlh1 gene known variants	1/1/2018
81294	Mlh1 gene dup/delete variant	1/1/2018
81295	Msh2 gene full seq	1/1/2018
81296	Msh2 gene known variants	1/1/2018
81297	Msh2 gene dup/delete variant	1/1/2018
81298	Msh6 gene full seq	1/1/2018
81299	Msh6 gene known variants	1/1/2018
81300	Msh6 gene dup/delete variant	1/1/2018



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81301	Microsatellite instability	1/1/2018
81302	Mecp2 gene full seq	1/1/2018
81303	Mecp2 gene known variant	1/1/2018
81304	Mecp2 gene dup/delet variant	1/1/2018
81310	Npm1 gene	1/1/2018
81311	Nras gene variants exon 2&3	1/1/2018
81313	Pca3/klk3 antigen	1/1/2018
81314	Pdgfra gene	1/1/2018
81315	Pml/raralpha com breakpoints	1/1/2018
81316	Pml/raralpha 1 breakpoint	1/1/2018
81317	Pms2 gene full seq analysis	1/1/2018
81318	Pms2 known familial variants	1/1/2018
81319	Pms2 gene dup/delet variants	1/1/2018
81321	Pten gene full sequence	1/1/2018
81322	Pten gene known fam variant	1/1/2018
81323	Pten gene dup/delet variant	1/1/2018
81324	Pmp22 gene dup/delet	1/1/2018
81325	Pmp22 gene full sequence	1/1/2018
81326	Pmp22 gene known fam variant	1/1/2018
81327	Sept9 methylation analysis	1/1/2018
81328	Slco1b1 gene com variants	1/1/2018
81330	Smpd1 gene common variants	1/1/2018
81331	Snrpn/ube3a gene	1/1/2018
81332	Serpina1 gene	1/1/2018
81334	Runx1 gene targeted seq alys	1/1/2018
81335	Tpmt gene com variants	1/1/2018
81340	Trb@ gene rearrange amplify	1/1/2018
81341	Trb@ gene rearrange dirprobe	1/1/2018
81342	Trg gene rearrangement anal	1/1/2018
81346	Tyms gene com variants	1/1/2018
81350	Ugt1a1 gene	1/1/2018
81355	Vkorc1 gene	1/1/2018
81361	Hbb gene com variants	1/1/2018
81362	Hbb gene known fam variant	1/1/2018
81363	Hbb gene dup/del variants	1/1/2018
81364	Hbb full gene sequence	1/1/2018
81370	Hla i & ii typing lr	1/1/2018



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81371	Hla i & ii type verify lr	1/1/2018
81372	Hla i typing complete lr	1/1/2018
81373	Hla i typing 1 locus lr	1/1/2018
81374	Hla i typing 1 antigen lr	1/1/2018
81375	Hla ii typing ag equiv lr	1/1/2018
81376	Hla ii typing 1 locus lr	1/1/2018
81377	Hla ii type 1 ag equiv lr	1/1/2018
81378	Hla i & ii typing hr	1/1/2018
81379	Hla i typing complete hr	1/1/2018
81380	Hla i typing 1 locus hr	1/1/2018
81381	Hla i typing 1 allele hr	1/1/2018
81382	Hla ii typing 1 loc hr	1/1/2018
81383	Hla ii typing 1 allele hr	1/1/2018
81400	Mopath procedure level 1	1/1/2018
81401	Mopath procedure level 2	1/1/2018
81402	Mopath procedure level 3	1/1/2018
81403	Mopath procedure level 4	1/1/2018
81404	Mopath procedure level 5	1/1/2018
81405	Mopath procedure level 6	1/1/2018
81406	Mopath procedure level 7	1/1/2018
81407	Mopath procedure level 8	1/1/2018
81408	Mopath procedure level 9	1/1/2018
81410	Aortic dysfunction/dilation	1/1/2018
81411	Aortic dysfunction/dilation	1/1/2018
81412	Ashkenazi jewish assoc dis	1/1/2018
81413	Car ion chnnlpath inc 10 gns	1/1/2018
81414	Car ion chnnlpath inc 2 gns	1/1/2018
81415	Exome sequence analysis	1/1/2018
81416	Exome sequence analysis	1/1/2018
81417	Exome re-evaluation	1/1/2018
81420	Fetal chromoml aneuploidy	1/1/2018
81422	Fetal chromoml microdeltj	1/1/2018
81425	Genome sequence analysis	1/1/2018
81426	Genome sequence analysis	1/1/2018
81427	Genome re-evaluation	1/1/2018
81430	Hearing loss sequence analys	1/1/2018
81431	Hearing loss dup/del analys	1/1/2018



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81432	Hrdtry brst ca-rlatd dsordrs	1/1/2018
81433	Hrdtry brst ca-rlatd dsordrs	1/1/2018
81434	Hereditary retinal disorders	1/1/2018
81435	Hereditary colon ca dsordrs	1/1/2018
81436	Hereditary colon ca dsordrs	1/1/2018
81437	Heredtry nurondcrn tum dsrd	1/1/2018
81438	Heredtry nurondcrn tum dsrd	1/1/2018
81439	Hrdtry cardmypy gene panel	1/1/2018
81440	Mitochondrial gene	1/1/2018
81442	Noonan spectrum disorders	1/1/2018
81445	Targeted genomic seq analys	1/1/2018
81448	Hrdtry perph neurphy panel	1/1/2018
81450	Targeted genomic seq analys	1/1/2018
81455	Targeted genomic seq analys	1/1/2018
81460	Whole mitochondrial genome	1/1/2018
81465	Whole mitochondrial genome	1/1/2018
81470	X-linked intellectual dblt	1/1/2018
81471	X-linked intellectual dblt	1/1/2018
81479	Unlisted molecular pathology	1/1/2018
81493	Cor artery disease mrna	1/1/2018
81504	Oncology tissue of origin	1/1/2018
81507	Fetal aneuploidy trisom risk	1/1/2018
81519	Oncology breast mrna	1/1/2018
81520	Onc breast mrna 58 genes	1/1/2018
81521	Onc breast mrna 70 genes	1/1/2018
81525	Oncology colon mrna	1/1/2018
81528	Oncology colorectal scr	1/1/2018
81540	Oncology tum unknown origin	1/1/2018
81541	Onc prostate mrna 46 genes	1/1/2018
81545	Oncology thyroid	1/1/2018
81551	Onc prostate 3 genes	1/1/2018
81595	Cardiology hrt trnspl mrna	1/1/2018
0004M	Scoliosis dna alys	1/1/2018
0006M	Onc hep gene risk classifier	1/1/2018
0007M	Onc gastro 51 gene nomogram	1/1/2018



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0008M	Onc breast risk score	Code deleted by the AMA on 12/31/2017
0009M	Fetal aneuploidy trisom risk	1/1/2018
0001U	Rbc dna hea 35 ag 11 bld grp	1/1/2018
0008U	Hpylori detcj abx rstnc dna	1/1/2018
0010U	Nfct ds strn typ whl gen seq	1/1/2018
0012U	Germln do gene reargmt detcj	1/1/2018
0013U	Onc sld org neo gene reargmt	1/1/2018
0014U	Hem hmtlmf neo gene reargmt	1/1/2018
0016U	Onc hmtlmf neo rna bcr/abl1	1/1/2018
0017U	Onc hmtlmf neo jak2 mut dna	1/1/2018
0018U	Onc thyr 10 microrna seq alg	1/1/2018
0019U	Onc rna tiss predict alg	1/1/2018
0022U	Trgt gen seq dna&rna 23 gene	1/1/2018
0023U	Onc aml dna detcj/nondetcj	1/1/2018
0011M	Onc prst8 ca mrna 12 gen alg	1/1/2018
0026U	Onc thyr dna&mrna 112 genes	1/1/2018
0027U	Jak2 gene trgt seq alys	1/1/2018
0028U	Cyp2d6 gene cpy nmr cmn vrnt	Code deleted by the AMA on 9/30/2018
0029U	Rx metab advrs trgt seq alys	1/1/2018
0030U	Rx metab warf trgt seq alys	1/1/2018
0031U	Cyp1a2 gene	1/1/2018
0032U	Comt gene	1/1/2018
0033U	Htr2a htr2c genes	1/1/2018
0034U	Tpmt nudt15 genes	1/1/2018
0012M	Onc mrna 5 gen rsk urthl ca	4/1/2018
0013M	Onc mrna 5 gen recr urthl ca	4/1/2018
0036U	Xome tum & nml spec seq alys	4/1/2018
0037U	Trgt gen seq dna 324 genes	4/1/2018
0040U	Bcr/abl1 gene major bp quan	4/1/2018
0045U	Onc brst dux carc is 12 gene	7/1/2018
0046U	Flt3 gene itd variants quan	7/1/2018
0047U	Onc prst8 mrna 17 gene alg	7/1/2018
0048U	Onc sld org neo dna 468 gene	7/1/2018
0049U	Npm1 gene analysis quan	7/1/2018



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0050U	Trgt gen seq dna 194 genes	7/1/2018
0053U	Onc prst8 ca fish alys 4 gen	7/1/2018
0055U	Card hrt trnspl 96 dna seq	7/1/2018
0056U	Hem aml dna gene reargmt	7/1/2018
0057U	Onc sld org neo mrna 51 gene	7/1/2018
0060U	Twn zyg gen seq alys chrms2	7/1/2018
0067U	Onc brst imhchem prfl 4 bmrk	10/1/2018
0069U	Onc clrct microrna mir-31-3p	10/1/2018
0070U	Cyp2d6 gen com&slct rar vrnt	10/1/2018
0078U	Pain mgt opi use gnotyp pnl	10/1/2018
81163	Brca1&2 gene full seq alys	1/1/2019
81164	Brca1&2 gen ful dup/del alys	1/1/2019
81165	Brca1 gene full seq alys	1/1/2019
81166	Brca1 gene full dup/del alys	1/1/2019
81167	Brca2 gene full dup/del alys	1/1/2019
81171	Aff2 gene detc abnor alleles	1/1/2019
81172	Aff2 gene charac alleles	1/1/2019
81173	Ar gene full gene sequence	1/1/2019
81174	Ar gene known famil variant	1/1/2019
81177	Atn1 gene detc abnor alleles	1/1/2019
81178	At1n1 gene detc abnor allele	1/1/2019
81179	At1n2 gene detc abnor allele	1/1/2019
81180	At1n3 gene detc abnor allele	1/1/2019
81181	At1n7 gene detc abnor allele	1/1/2019
81182	At1n8os gen detc abnor allele	1/1/2019
81183	At1n10 gene detc abnor allele	1/1/2019
81184	Cacna1a gen detc abnor allele	1/1/2019
81185	Cacna1a gene full gene seq	1/1/2019
81186	Cacna1a gen known famil vrnt	1/1/2019
81187	Cnbp gene detc abnor allele	1/1/2019
81188	Cstb gene detc abnor allele	1/1/2019
81189	Cstb gene full gene sequence	1/1/2019
81190	Cstb gene known famil vrnt	1/1/2019
81201	Apc gene full sequence	1/1/2019
81204	Ar gene charac alleles	1/1/2019
81233	Btk gene common variants	1/1/2019
81234	Dmpk gene detc abnor allele	1/1/2019



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81236	Ezh2 gene full gene sequence	1/1/2019
81237	Ezh2 gene common variants	1/1/2019
81239	Dmpk gene charac alleles	1/1/2019
81271	Htt gene detc abnor alleles	1/1/2019
81274	Htt gene charac alleles	1/1/2019
81284	F1n gene detc abnor alleles	1/1/2019
81285	F1n gene charac alleles	1/1/2019
81286	F1n gene full gene sequence	1/1/2019
81289	F1n gene known famil variant	1/1/2019
81305	Myd88 gene p.leu265pro vrnt	1/1/2019
81306	Nudt15 gene common variants	1/1/2019
81312	Pabpn1 gene detc abnor allele	1/1/2019
81320	Plcg2 gene common variants	1/1/2019
81329	Smn1 gene dos/deletion alys	1/1/2019
81333	Tgfb1 gene common variants	1/1/2019
81336	Smn1 gene full gene sequence	1/1/2019
81337	Smn1 gen nown famil seq vrnt	1/1/2019
81343	Ppp2r2b gen detc abnor allele	1/1/2019
81344	Tbp gene detc abnor alleles	1/1/2019
81345	Tert gene targeted seq alys	1/1/2019
81443	Genetic tstg severe inh cond	1/1/2019
81518	Onc brst mrna 11 genes	1/1/2019
81596	Nfct ds chrnc hcv 6 assays	1/1/2019
81538	Oncology lung	1/1/2019

If you have any questions about this information, please contact your Practice Manager.