People. Trust. Results.
Since 1960

UPDATE to the 14 Day Rule Exception for Outpatient Molecular Tests and Advanced Diagnostic Laboratory Tests

Earlier this year, we posted our white paper, ***The New Year Rings-In Change to CMS' "14 Day Rule" for Its Laboratory Date of Service Policy*** that detailed the criteria required to be exempt from Medicare's **14 Day Rule** for hospital outpatients that receive certain pathology molecular testing and advanced diagnostic lab tests following discharge from the hospital outpatient department. The list of CPT codes included in the exemption effective January 1, 2018, was included in the article.

To summarize, prior to 2018 the 14 Day Rule prevented reference and independent laboratories from billing Medicare directly for molecular pathology and advanced diagnostic lab tests ordered less than 14 days following an outpatient's discharge from the hospital. The lab would have to seek its share of the reimbursement for the testing from the hospital.

The exemption stated that, for the listed CPT codes, **the date of service (DOS) for the test must be the date the test was performed,** not the date the specimen was obtained as is the usual policy. This effectively separates the lab test from the hospital outpatient encounter, meaning the lab that performed the test now bills (and receives payment from) Medicare directly. **The following conditions must be met:**

- The physician orders the test following the date of a hospital outpatient's discharge from the hospital outpatient department
- The specimen was collected from a hospital outpatient, not an inpatient, during an encounter
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter
- The results of the test do not guide treatment provided during the hospital outpatient encounter
- The test was reasonable and medically necessary for the treatment of an illness

CMS has since added to the list of applicable CPT codes; **of note is the addition of some Genomic Sequencing (GSP) and Multianalyte Assays with Algorithmic Analyses (MAAAs) codes.** According to its Laboratory Date of Service Policy webpage, the list of codes will be updated on a quarterly basis – the list of CPT codes from the June 25, 2018, update follows. Please visit the link to view the HCPCS Proprietary codes included.

Information provided by APS Medical Billing, August 2018

People. Trust. Results.
Since 1960

CPT Code	Short Descriptor	CPT Code	Short Descriptor
81105	Hpa-1 genotyping	81310	Npm1 gene
81106	Hpa-2 genotyping	81311	Nras gene variants exon 2&3
81107	Hpa-3 genotyping	81313	Pca3/klk3 antigen
81108	Hpa-4 genotyping	81314	Pdgfra gene
81109	Hpa-5 genotyping	81315	Pml/raralpha com breakpoints
81110	Hpa-6 genotyping	81316	Pml/raralpha 1 breakpoint
81111	Hpa-9 genotyping	81317	Pms2 gene full seq analysis
81112	Hpa-15 genotyping	81318	Pms2 known familial variants
81120	Idh1 common variants	81319	Pms2 gene dup/delet variants
81121	Idh2 common variants	81321	Pten gene full sequence
81161	Dmd dup/delet analysis	81322	Pten gene known fam variant
81162	Brca1&2 seq & full dup/del	81323	Pten gene dup/delet variant
81170	Abl1 gene	81324	Pmp22 gene dup/delet
81175	Asxl1 full gene sequence	81325	Pmp22 gene full sequence
81176	Asxl1 gene target seq alys	81326	Pmp22 gene known fam variant
81200	Aspa gene	81327	Sept9 methylation analysis
81201	Apc gene full sequence	81328	Slco1b1 gene com variants
81202	Apc gene known fam variants	81330	Smpd1 gene common variants
81203	Apc gene dup/delet variants	81331	Snrpn/ube3a gene
81205	Bckdhb gene	81332	Serpina1 gene
81206	Bcr/abl1 gene major bp	81334	Runx1 gene targeted seq alys
81207	Bcr/abl1 gene minor bp	81335	Tpmt gene com variants
81208	Bcr/abl1 gene other bp	81340	Trb@ gene rearrange amplify
81209	Blm gene	81341	Trb@ gene rearrange dirprobe
81210	Braf gene	81342	Trg gene rearrangement anal
81211	Brca1&2 seq & com dup/del	81346	Tyms gene com variants
81212	Brca1&2 185&5385&6174 var	81350	Ugt1a1 gene
81213	Brca1&2 uncom dup/del var	81355	Vkorc1 gene
81214	Brca1 full seq & com dup/del	81361	Hbb gene com variants
81215	Brca1 gene known fam variant	81362	Hbb gene known fam variant
81216	Brca2 gene full sequence	81363	Hbb gene dup/del variants
81217	Brca2 gene known fam variant	81364	Hbb full gene sequence
81218	Cebpa gene full sequence	81370	Hla i & ii typing lr
81219	Calr gene com variants	81371	Hla i & ii type verify lr
81220	Cftr gene com variants	81372	Hla i typing complete lr
81221	Cftr gene known fam variants	81373	Hla i typing 1 locus lr
81222	Cftr gene dup/delet variants	81374	Hla i typing 1 antigen lr
81223	Cftr gene full sequence	81375	Hla ii typing ag equiv lr
81224	Cftr gene intron poly t	81376	Hla ii typing 1 locus lr
81225	Cyp2c19 gene com variants	81377	Hla ii type 1 ag equiv lr
81226	Cyp2d6 gene com variants	81378	Hla i & ii typing hr

Information provided by APS Medical Billing, August 2018

People. Trust. Results.
Since 1960

CPT Code	Short Descriptor	CPT Code	Short Descriptor
81227	Cyp2c9 gene com variants	81379	Hla i typing complete hr
81228	Cytogen micrarray copy nmbr	81380	Hla i typing 1 locus hr
81229	Cytogen m array copy no&snp	81381	Hla i typing 1 allele hr
81230	Cyp3a4 gene common variants	81382	Hla ii typing 1 loc hr
81231	Cyp3a5 gene common variants	81383	Hla ii typing 1 allele hr
81232	Dpyd gene common variants	81400	Mopath procedure level 1
81235	Egfr gene com variants	81401	Mopath procedure level 2
81238	F9 full gene sequence	81402	Mopath procedure level 3
81240	F2 gene	81403	Mopath procedure level 4
81241	F5 gene	81404	Mopath procedure level 5
81242	Fancc gene	81405	Mopath procedure level 6
81243	Fmr1 gene detection	81406	Mopath procedure level 7
81244	Fmr1 gene characterization	81407	Mopath procedure level 8
81245	Flt3 gene	81408	Mopath procedure level 9
81246	Flt3 gene analysis	81410	Aortic dysfunction/dilation
81247	G6pd gene alys cmn variant	81411	Aortic dysfunction/dilation
81248	G6pd known familial variant	81412	Ashkenazi jewish assoc dis
81249	G6pd full gene sequence	81413	Car ion chnnlpath inc 10 gns
81250	G6pc gene	81414	Car ion chnnlpath inc 2 gns
81251	Gba gene	81415	Exome sequence analysis
81252	Gjb2 gene full sequence	81416	Exome sequence analysis
81253	Gjb2 gene known fam variants	81417	Exome re-evaluation
81254	Gjb6 gene com variants	81420	Fetal chrmoml aneuploidy
81255	Hexa gene	81422	Fetal chrmoml microdeltj
81256	Hfe gene	81425	Genome sequence analysis
81257	Hba1/hba2 gene	81426	Genome sequence analysis
81258	Hba1/hba2 gene fam vrnt	81427	Genome re-evaluation
81259	Hba1/hba2 full gene sequence	81430	Hearing loss sequence analys
81260	Ikbkap gene	81431	Hearing loss dup/del analys
81261	Igh gene rearrange amp meth	81432	Hrdtry brst ca-rlatd dsordrs
81262	Igh gene rearrang dir probe	81433	Hrdtry brst ca-rlatd dsordrs
81263	Igh vari regional mutation	81434	Hereditary retinal disorders
81264	Igk rearrangeabn clonal pop	81435	Hereditary colon ca dsordrs
81265	Str markers specimen anal	81436	Hereditary colon ca dsordrs
81266	Str markers spec anal addl	81437	Heredtry nurondcrn tum dsrdr
81267	Chimerism anal no cell selec	81438	Heredtry nurondcrn tum dsrdr
81268	Chimerism anal w/cell select	81439	Hrdtry cardmypy gene panel
81269	Hba1/hba2 gene dup/del vrnts	81440	Mitochondrial gene
81270	Jak2 gene	81442	Noonan spectrum disorders
81272	Kit gene targeted seq analys	81445	Targeted genomic seq analys
81273	Kit gene analys d816 variant	81448	Hrdtry perph neurphy panel

Information provided by APS Medical Billing, August 2018

People. Trust. Results.
Since 1960

CPT Code	Short Descriptor	CPT Code	Short Descriptor
81275	Kras gene variants exon 2	81450	Targeted genomic seq analys
81276	Kras gene addl variants	81455	Targeted genomic seq analys
81283	Ifnl3 gene	81460	Whole mitochondrial genome
81287	Mgmt gene methylation anal	81465	Whole mitochondrial genome
81288	Mlh1 gene	81470	X-linked intellectual dblt
81290	Mcoln1 gene	81471	X-linked intellectual dblt
81291	Mthfr gene	81479	Unlisted molecular pathology
81292	Mlh1 gene full seq	81493	Cor artery disease mrna
81293	Mlh1 gene known variants	81504	Oncology tissue of origin
81294	Mlh1 gene dup/delete variant	81507	Fetal aneuploidy trisom risk
81295	Msh2 gene full seq	81519	Oncology breast mrna
81296	Msh2 gene known variants	81520	Onc breast mrna 58 genes
81297	Msh2 gene dup/delete variant	81521	Onc breast mrna 70 genes
81298	Msh6 gene full seq	81525	Oncology colon mrna
81299	Msh6 gene known variants	81528	Oncology colorectal scr
81300	Msh6 gene dup/delete variant	81540	Oncology tum unknown origin
81301	Microsatellite instability	81541	Onc prostate mrna 46 genes
81302	Mecp2 gene full seq	81545	Oncology thyroid
81303	Mecp2 gene known variant	81551	Onc prostate 3 genes
81304	Mecp2 gene dup/delet variant	81595	Cardiology hrt trnspl mrna

Should you have any questions, please contact your Practice Manager.