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The New Year Rings-In Change to CMS' "14 Day Rule" for Its Laboratory Date of Service Policy

Prior to 2018, CMS' 14 Day Rule prevented reference and independent laboratories from billing Medicare directly for molecular pathology tests ordered less than 14 days following an outpatient's discharge from the hospital. Instead, the laboratory would seek reimbursement from the hospital and the hospital would bill Medicare.

Although molecular tests were not bundled into hospital payment packages by the Hospital Outpatient Prospective Payment System (OPPS) fee schedule, CMS treated them as such when they were ordered within 14 days of a patient's discharge.

A main factor in the issue is CMS' Date of Service (DOS) policy, which generally requires that the DOS for clinical diagnostic laboratory services is the date the specimen is collected. Medicare has been clear that the DOS may affect payment for a test, especially when the specimen was collected while the patient was being treated in the hospital and is later used for testing after the patient has been discharged.

Besides the obvious administrative challenges this represents for both labs and hospitals, there has been growing clinical concern voiced over potential delays in patient testing, access to test results, and implementation of treatment plans as the 14 day timeframe is accommodated.

In response, the 2018 CMS OPPS Final Rule created an exception to the 14 Day Rule and modified its DOS Policy specifically for hospital outpatients receiving MolDX Tier 1 and Tier 2 molecular tests and advanced diagnostic laboratory tests (ADLT).

Effective January 1, 2018, in the case of the above tests, the DOS must be the date the test was performed instead of the date the specimen was obtained, as long as the following conditions are 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 during an outpatient encounter
- It would be medically inappropriate to have collected the sample from the hospital outpatient other than 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

This revision now enables labs performing specific molecular pathology tests to bill Medicare directly instead of seeking reimbursement from the hospital.

It is important to note the following exceptions to this laboratory DOS change:

1. The exception only applies when the specimen has been obtained from a hospital outpatient, not inpatient
2. The exception does not apply to Gene Sequencing procedures (GSPs), Proprietary Laboratory Analysis tests (PLAs), or Protein-based Molecular Multi-Analyte Assays with Algorithmic Analysis (MAAAs); hospitals will continue billing Medicare for these tests when ordered less than 14 days following a hospital outpatient's discharge.

On the following pages is a comprehensive list of all molecular tests that are exempt from the 14 day DOS rule.

Information provided by APS Medical Billing, January 2018

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MolDX Tier 1 and Tier 2 CPT Codes Subject to Laboratory DOS and 14 Day Rule Changes 2018 OPPS Payment Schedule – Addendum B			
81105	Hpa-1 genotyping	**81270**	Jak2 gene
81106	Hpa-2 genotyping	**81272**	Kit gene targeted seq analys
81107	Hpa-3 genotyping	**81273**	Kit gene analys d816 variant
81108	Hpa-4 genotyping	**81275**	Kras gene variants exon 2
81109	Hpa-5 genotyping	**81276**	Kras gene addl variants
81110	Hpa-6 genotyping	**81283**	Ifnl3 gene
81111	Hpa-9 genotyping	**81287**	Mgmt gene methylation anal
81112	Hpa-15 genotyping	**81288**	Mlh1 gene
81120	Idh1 common variants	**81290**	Mcoln1 gene
81121	Idh2 common variants	**81291**	Mthfr gene
81161	Dmd dup/delet analysis	**81292**	Mlh1 gene full seq
81162	Brca1&2 seq & full dup/del	**81293**	Mlh1 gene known variants
81170	Abl1 gene	**81294**	Mlh1 gene dup/delete variant
81175	Asxl1 full gene sequence	**81295**	Msh2 gene full seq
81176	Asxl1 gene target seq alys	**81296**	Msh2 gene known variants
81200	Aspa gene	**81297**	Msh2 gene dup/delete variant
81201	Apc gene full sequence	**81298**	Msh6 gene full seq
81202	Apc gene known fam variants	**81299**	Msh6 gene known variants
81203	Apc gene dup/delet variants	**81300**	Msh6 gene dup/delete variant
81205	Bckdhb gene	**81301**	Microsatellite instability
81206	Bcr/abl1 gene major bp	**81302**	Mecp2 gene full seq
81207	Bcr/abl1 gene minor bp	**81303**	Mecp2 gene known variant
81208	Bcr/abl1 gene other bp	**81304**	Mecp2 gene dup/delet variant
81209	Blm gene	**81310**	Npm1 gene
81210	Braf gene	**81311**	Nras gene variants exon 2&3
81211	Brca1&2 seq & com dup/del	**81313**	Pca3/klk3 antigen
81212	Brca1&2 185&5385&6174 var	**81314**	Pdgfra gene
81213	Brca1&2 uncom dup/del var	**81315**	Pml/raralpha com breakpoints
81214	Brca1 full seq & com dup/del	**81316**	Pml/raralpha 1 breakpoint
81215	Brca1 gene known fam variant	**81317**	Pms2 gene full seq analysis
81216	Brca2 gene full sequence	**81318**	Pms2 known familial variants
81217	Brca2 gene known fam variant	**81319**	Pms2 gene dup/delet variants
81218	Cebpa gene full sequence	**81321**	Pten gene full sequence
81219	Calr gene com variants	**81322**	Pten gene known fam variant
81220	Cftr gene com variants	**81323**	Pten gene dup/delet variant
81221	Cftr gene known fam variants	**81324**	Pmp22 gene dup/delet
81222	Cftr gene dup/delet variants	**81325**	Pmp22 gene full sequence
81223	Cftr gene full sequence	**81326**	Pmp22 gene known fam variant
81224	Cftr gene intron poly t	**81327**	Sept9 methylation analysis

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81225	Cyp2c19 gene com variants	**81328**	Slco1b1 gene com variants
81226	Cyp2d6 gene com variants	**81330**	Smpd1 gene common variants
81227	Cyp2c9 gene com variants	**81331**	Snrpn/ube3a gene
81228	Cytogen micrarray copy nmbr	**81332**	Serpina1 gene
81229	Cytogen m array copy no&snp	**81334**	Runx1 gene targeted seq alys
81230	Cyp3a4 gene common variants	**81335**	Tpmt gene com variants
81231	Cyp3a5 gene common variants	**81340**	Trb@ gene rearrange amplify
81232	Dpyd gene common variants	**81341**	Trb@ gene rearrange dirprobe
81235	Egfr gene com variants	**81342**	Trg gene rearrangement anal
81238	F9 full gene sequence	**81346**	Tyms gene com variants
81240	F2 gene	**81350**	Ugt1a1 gene
81241	F5 gene	**81355**	Vkorc1 gene
81242	Fancc gene	**81361**	Hbb gene com variants
81243	Fmr1 gene detection	**81362**	Hbb gene known fam variant
81244	Fmr1 gene characterization	**81363**	Hbb gene dup/del variants
81245	Flt3 gene	**81364**	Hbb full gene sequence
81246	Flt3 gene analysis	**81370**	Hla i & ii typing lr
81247	G6pd gene alys cmn variant	**81371**	Hla i & ii type verify lr
81248	G6pd known familial variant	**81372**	Hla i typing complete lr
81249	G6pd full gene sequence	**81373**	Hla i typing 1 locus lr
81250	G6pc gene	**81374**	Hla i typing 1 antigen lr
81251	Gba gene	**81375**	Hla ii typing ag equiv lr
81252	Gjb2 gene full sequence	**81376**	Hla ii typing 1 locus lr
81253	Gjb2 gene known fam variants	**81377**	Hla ii type 1 ag equiv lr
81254	Gjb6 gene com variants	**81378**	Hla i & ii typing hr
81255	Hexa gene	**81379**	Hla i typing complete hr
81256	Hfe gene	**81380**	Hla i typing 1 locus hr
81257	Hba1/hba2 gene	**81381**	Hla i typing 1 allele hr
81258	Hba1/hba2 gene fam vrnt	**81382**	Hla ii typing 1 loc hr
81259	Hba1/hba2 full gene sequence	**81383**	Hla ii typing 1 allele hr
81260	Ikbkap gene	**81400**	Mopath procedure level 1
81261	Igh gene rearrange amp meth	**81401**	Mopath procedure level 2
81262	Igh gene rearrang dir probe	**81402**	Mopath procedure level 3
81263	Igh vari regional mutation	**81403**	Mopath procedure level 4
81264	Igk rearrangeabn clonal pop	**81404**	Mopath procedure level 5
81265	Str markers specimen anal	**81405**	Mopath procedure level 6
81266	Str markers spec anal addl	**81406**	Mopath procedure level 7
81267	Chimerism anal no cell selec	**81407**	Mopath procedure level 8
81268	Chimerism anal w/cell select	**81408**	Mopath procedure level 9
81269	Hba1/hba2 gene dup/del vrnts	**81479**	Unlisted molecular pathology

Please contact your APS Practice Manager with any questions you may have regarding this correspondence.