

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



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MLN Matters® Number: MM8162

Related Change Request (CR) #: CR 8162

Related CR Release Date: January 25, 2013

Effective Date: January 1, 2013

Related CR Transmittal #: R2639CP

Implementation Date: April 1, 2013

Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits

Provider Types Affected

This MLN Matters® Article is intended for clinical diagnostic laboratories submitting claims to Medicare contractors (carriers and A/B Medicare Administrative Contractors (MACs)) for services to Medicare beneficiaries.

Provider Action Needed

This article is based on Change Request (CR) 8162, which informs Medicare contractors about the new Healthcare Common Procedure Coding System (HCPCS) codes for 2013 that are both subject to and excluded from Clinical Laboratory Improvement Amendments (CLIA) edits. The CR also lists the HCPCS codes discontinued as of December 31, 2012.

Make sure that your billing staffs are aware of these CLIA-related changes for 2013 and that you remain current with CLIA certification requirements.

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Background

The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that the Medicare and Medicaid Programs only pay for laboratory tests performed in certified facilities, each claim for a HCPCS code that is considered a CLIA laboratory test is currently edited at the CLIA certificate level.

The HCPCS codes that are considered a laboratory test under CLIA change each year. Contractors need to be informed about the new HCPCS codes that are both subject to CLIA edits and excluded from CLIA edits.

Discontinued Codes

The following HCPCS codes were discontinued on December 31, 2012:

HCPCS	Description
83890	Molecular diagnostics; molecular isolation or extraction, each nucleic acid type (i.e., DNA or RNA)
83891	Molecular diagnostics; isolation or extraction of highly purified nucleic acid, each nucleic acid type (i.e., DNA or RNA)
83892	Molecular diagnostics; enzymatic digestion, each enzyme treatment
83893	Molecular diagnostics; dot/slot blot production, each nucleic acid preparation,
83894	Molecular diagnostics; separation by gel electrophoresis (e.g., agarose, polyacrylamide), each nucleic acid preparation
83896	Molecular diagnostics; nucleic acid probe, each
83897	Molecular diagnostics; nucleic acid transfer (e.g., southern, northern), each nucleic acid preparation
83898	Molecular diagnostics; amplification, target, each nucleic acid sequence
83900	Molecular diagnostics; amplification, target, multiplex, first 2 nucleic acid sequences
83901	Molecular diagnostics; amplification, target, multiplex, each additional nucleic acid sequence beyond 2 (list separately in addition to code for primary procedure)
83902	Molecular diagnostics; reverse transcription
83903	Molecular diagnostics; mutation scanning, by physical properties (e.g., single strand conformational polymorphisms [sscp], heteroduplex, denaturing gradient gel electrophoresis [DGGE], RNA'ASE a), single segment, each
83904	Molecular diagnostics; mutation identification by sequencing, single segment, each segment
83905	Molecular diagnostics; mutation identification by allele specific transcription, single segment, each segment
83906	Molecular diagnostics; mutation identification by allele specific translation, single segment, each segment
83907	Molecular diagnostics; lysis of cells prior to nucleic acid extraction (e.g., stool specimens, paraffin embedded tissue), each specimen

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HCPCS	Description
83908	Molecular diagnostics; amplification, signal, each nucleic acid sequence
83909	Molecular diagnostics; separation and identification by high resolution technique (e.g., capillary electrophoresis), each nucleic acid preparation
83912	Molecular diagnostics; interpretation and report
83913	Molecular diagnostics; RNA stabilization
83914	Mutation identification by enzymatic ligation or primer extension, single segment, each segment (e.g., oligonucleotide ligation assay [OLA], single base chain extension [SBCE], or allele-specific primer extension [ASPE])
88384	Array-based evaluation of multiple molecular probes; 11 through 50 probes
88385	Array-based evaluation of multiple molecular probes; 51 through 250 probes
88386	Array-based evaluation of multiple molecular probes; 251 through 500 probes
0030T	Antiprothrombin (phospholipid cofactor) antibody, each IG class
0279T	Cell enumeration using immunologic selection and identification in fluid specimen (e.g., circulating tumor cells in blood)
0280T	Cell enumeration using immunologic selection and identification in fluid specimen (e.g., circulating tumor cells in blood); interpretation and report

New Codes for 2013

In 2012, there were 101 new HCPCS codes for molecular pathology (i.e., 81200 through 81408) that were subject to the CLIA regulations, were not payable by Medicare and were not included in the recurring update notification for 2012 (i.e., Change Request 7778). For 2013, these 101 molecular HCPCS codes have been placed on the Medicare Clinical Laboratory Fee Schedule. The 101 are included in the attachment to CR8162.

The HCPCS codes listed below are new for 2013 and are subject to CLIA edits. The list does not include new HCPCS codes for waived tests or provider-performed procedures. The HCPCS codes listed below require a facility to have either a CLIA certificate of registration (certificate type code 9), a CLIA certificate of compliance (certificate type code 1), or a CLIA certificate of accreditation (certificate type code 3). A facility without a valid, current, CLIA certificate, with a current CLIA certificate of waiver (certificate type code 2) or with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4) must not be permitted to be paid for these tests.

The new HCPCS codes for 2013 are the following:

- 81201 - APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; full gene sequence,
- 81202 - APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; known familial variants,

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- 81203 - APC (adenomatous polyposis coli) (eg, familial adenomatosis polyposis [FAP], attenuated FAP) gene analysis; duplication/deletion variants,
- 81235 - EGFR (epidermal growth factor receptor) (eg, non-small cell lung cancer) gene analysis, common variants (eg, exon 19 Irea deletion, L858R, T790M, G719A, G719S, L861Q),
- 81252 - GJB2 (gap junction protein, beta 2, 26kDa; Connexin 26) (eg, nonsyndromic hearing loss) gene analysis; full gene sequence,
- 81253 - GJB2 (gap junction protein, beta 2, 26kDa; known familial variants,
- 81254 - GJB6 (gap junction protein, beta 6, 30 kDa, Connexin 30) (eg, nonsyndromic hearing loss) gene analysis, common variants (eg, 309KB [DEL(GJB6-D13S1830)] and 232KB [DEL(GJB6-D13S1854)]),
- 81321 - PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; full sequence analysis,
- 81322 - PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; known familial variant,
- 81323 - PTEN (phosphatase and tensin homolog) (eg, Cowden syndrome, PTEN hamartoma tumor syndrome) gene analysis; duplication/deletion variant,
- 81324 - PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; duplication/deletion analysis,
- 81325 - PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; full sequence analysis,
- 81326 - PMP22 (peripheral myelin protein 22) (eg, Charcot-Marie-Tooth, hereditary neuropathy with liability to pressure palsies) gene analysis; known familial variant,
- 81479 - Unlisted molecular pathology procedure,
- 82777 - Galectin-3,
- 86152 - Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood),
- 86153 - Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood); physician interpretation and report, when required,
- 86711 - JC (John Cunningham) virus,
- 86828 - Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads; ELISA, flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I and Class II HLA antigens,
- 86829 - Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); qualitative assessment of the presence or absence of antibody(ies) to HLA Class I or Class II HLA antigens,
- 86830 - Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); antibody identification by qualitative panel using complete HLA phenotypes, HLA Class I,
- 86831 - Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); antibody identification by qualitative panel using complete HLA phenotypes, HLA Class II,

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- 86832 - Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class I,
- 86833 - Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); high definition qualitative panel for identification of antibody specificities (eg, individual antigen per bead methodology), HLA Class II,
- 86834 - Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); semi-quantitative panel (eg, titer), HLA Class I,
- 86835 - Antibody to human leukocyte antigens (HLA), solid phase assays (eg, microspheres or beads, ELISA, flow cytometry); semi-quantitative panel (eg, titer), HLA Class II,
- 87631 - Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 3-5 targets,
- 87632 - Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 6-11 targets,
- 87633 - Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), multiplex reverse transcription and amplified probe technique, multiple types or subtypes, 12-25 targets,
- 87910 - Infectious agent genotype analysis by nucleic acid (DNA or RNA); cytomegalovirus,
- 87912 - Infectious agent genotype analysis by nucleic acid (DNA or RNA); Hepatitis B virus, and
- 88375 - Optical endoscopic image(s), interpretation and report, real-time or referred, each endoscopic session.

Additionally, there were 9 new HCPCS codes for multi-analyte assays with algorithmic analyses (i.e., 81500 through 81512, and 81599) in 2013. The testing described by these codes is subject to the CLIA regulations, however, they are not payable by Medicare for CY 2013. Hence, these 9 codes were not included in CR8162.

Additional Information

The official instruction, CR 8162, issued to your carrier and A/B MAC regarding this change may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2639CP.pdf> on the CMS website.

If you have any questions, please contact your carrier or A/B MAC at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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