



News Flash – The Centers for Medicare & Medicaid Services (CMS) reminds all providers, physicians, and suppliers to allow sufficient time for the Medicare crossover process to work—approximately 15 work days after Medicare’s reimbursement is made, as stated in MLN Matters Article SE0909 (<http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0909.pdf>) — before attempting to balance bill their patients’ supplemental insurers. That is, do not balance bill until you have received written confirmation from Medicare that your patients’ claims will not be crossed over, or you have received a special notification letter explaining why specified claims cannot be crossed over. Remittance Advice Remark Codes MA18 or N89 on your Medicare Remittance Advice (MRA) represent Medicare’s intention to cross your patients’ claims over.

MLN Matters® Number: MM6812 **Revised**

Related Change Request (CR) #: 6812

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

Note: This article was revised on May 17, 2011 to add a reference to MLN Matters® article MM7325 (<http://www.cms.gov/MLNMattersArticles/downloads/MM7325.pdf>), which reiterates the policy that states that no CLIA certificate is required for a claim submitted for any test mentioned in the HCPCS 80000 series codes that are excluded from the CLIA edits list. Contractors must ensure that codes on this list are not subject to CLIA edits. All other information is the same.

Provider Types Affected

Clinical laboratories and providers that submit claims to Medicare carriers or Medicare Administrative Contractors (MACs) for laboratory test services provided to Medicare beneficiaries may be impacted by this issue.

Provider Action Needed

CR 6812, from which this article is taken, informs your carriers and MACs about the new HCPCS codes for 2010 that are subject to, and those that are excluded from, CLIA edits. Please see the Background section, below, for details.

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Background

The Clinical Laboratory Improvement Amendments (CLIA) regulations require a facility to be appropriately certified for each test it performs; and moreover, to ensure that Medicare & Medicaid only pay for laboratory tests that are 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.

Since the HCPCS codes that are considered a laboratory test under CLIA change each year, the Center for Medicare & Medicaid Services (CMS) needs to inform carriers and MACs about the new HCPCS codes that are subject to CLIA edits and those that are excluded from CLIA edits. CR 6812, from which this article is taken, provides them this information for 2010.

HCPCS Codes Subject to CLIA Edits

The HCPCS codes listed in the following table are new for 2010 and are subject to CLIA edits; and 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, or with a current CLIA certificate of waiver (certificate type code 2) or a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4) must not be permitted to be paid for these tests.

The table does not include new HCPCS codes for waived tests or provider-performed procedures.

HCPCS	Description
G0430	Drug screen qualitative; multiple drug classes other than chromographic method, each procedure
G0431	Drug screen qualitative; single drug class method (e.g., immunoassay), each drug class
84145	Procalcitonin (PCT)
84431	Thromboxane metabolite(s), including thromboxane , if performed, urine
86305	Human epididymis protein 4 (HE4)
86352	Cellular function assay involving stimulation (e.g., mitogen or antigen) and detection of biomarker (e.g., APT)

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HCCPS	Description
86780	Antibody; Treponema pallidum
86825	Human leukocyte antigen (HLA) crossmatch, non-cytotoxic (e.g., using flow cytometry); first serum sample or dilution
86826	Human leukocyte antigen (HLA) crossmatch, non-cytotoxic (e.g., using flow cytometry); each additional serum sample or sample dilution (List separately in addition to primary procedure)
87150	Culture, typing; identification by nucleic acid (DNA or RNA) amplified probe technique, per culture or isolate, each organism probed
87153	Culture, typing; identification by nucleic acid sequencing method; each isolate (e.g., sequencing of 16S rRNA gene)
87493	Infectious agent detection by nucleic acid (DNA or RNA); Clostridium difficile toxin gene(s), amplified probe technique
88387	Macroscopic examination, dissection, and preparation of tissue for non-microscopic analytical studies (e.g., nucleic acid-based molecular studies); each tissue preparation (e.g., a single lymph node)
88388	Macroscopic examination, dissection, and preparation of tissue for non-microscopic analytical studies (e.g., nucleic acid-based molecular studies); in conjunction with a touch imprint, intraoperative consultation, or frozen section, each tissue preparation (e.g., a single lymph node) (list separately in addition to code for primary procedure)

Discontinued HCPCS Codes

The following HCPCS codes were discontinued on December 31, 2009:

- 82307 – Calciferol (Vitamin D);
- 86781 – Antibody; Treponema pallidum confirmatory test (e.g., FTA-ABS); and
- 0087T – Sperm evaluation, hyaluronan sperm binding test.

New Codes Excluded from CLIA Edits

For 2010, the following HCPCS codes are new and excluded from CLIA edits and do not require a facility to have any CLIA certificate:

- 83987 – pH; exhaled breath condensate;
- 88738 – Hemoglobin (Hgb), quantitative, transcutaneous; and
- 89398 – Unlisted reproductive medicine laboratory procedure.

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Additional Information

You should be aware that your carriers or MACs will return (as unprocessable) claims that you submit for the HCPCS codes in the above table (those subject to CLIA edits), if you don't include a CLIA number. Further, while they are not required to search their files to either retract payment for claims already paid or to retroactively pay claims processed prior to implementation of CR 6812, your carrier or MAC will adjust claims that you bring to their attention.

You can find the official instruction, CR6812, issued to your carrier or MAC by visiting <http://www.cms.hhs.gov/Transmittals/downloads/R1912CP.pdf> on the CMS website.

If you have any questions, please contact your carrier or MAC at their toll-free number, which may be found at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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