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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 August 27, 2007, to inform providers that CR5113 notified carriers of a HCPCS correction for code 89049 (page 5). Effective January 1, 2006, carriers removed CLIA edits for HCPCS code 89049, including the laboratory certification code 610 (histopathology), and will not require a CLIA number on claims submitted by facilities for the HCPCS code 89049. For the details of this change providers should view CR5113 at <http://www.cms.hhs.gov/Transmittals/downloads/R984CP.pdf> on the CMS web site. The related MLN Matters article may be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/mm5113.pdf> on the CMS website.

### Provider Types Affected

Providers and clinical laboratories that submit claims to Medicare carriers for CLIA-related services

### Key Points

The HCPCS codes that are considered laboratory tests under CLIA are subject to change each year. Effective January 1, 2006, there are new HCPCS codes,

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including modifiers, for 2006 that are either subject to CLIA edits or excluded from CLIA edits.

HCPCS codes subject to or excluded from CLIA edits are described in Change Request (CR) 4321 and in the attachments to that CR which revise the *Medicare Claims Processing Manual* (Publication 100-04), Chapter 16, Laboratory Services.

The new 2006 HCPCS codes are listed in Table 1, Appendix A, of this article. Please note that this list **does not** include new HCPCS codes for waived tests or provider-performed procedures.

These HCPCS codes are subject to CLIA edits, therefore a CLIA number must be submitted on claims by facilities for these HCPCS codes. The HCPCS codes listed in the Table 1 **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).

Facilities will not be permitted to bill for the tests listed in Table 1, Appendix A, of this article:

- If they **do not have** a valid, current, CLIA certificate;
- If they **have** a current CLIA certificate of waiver (certificate type code 2); **or**
- If they **have** a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4).

Effective January 19, 1993, a laboratory that holds a certificate for provider-performed microscopy procedures may perform only those tests specified as provider-performed microscopy procedures and waived tests, and no others. The provider-performed microscopy procedures are described in Table 2, Appendix A of this article.

The following new HCPCS codes for 2006 in the 80000 series are excluded from CLIA edits and **do not require** a facility to have any CLIA certificate:

- 86923 - Compatibility test each unit; electronic;
- 86960 - Volume reduction of blood or blood products (e.g., red blood cells or platelets), each unit; and
- 87900 - Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics.

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## Relevant Links

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For a complete list of the specific HCPCS codes subject to CLIA edits please refer to <http://www.cms.hhs.gov/CLIA/downloads/Subject.to.CLIA.pdf> on the Centers for Medicare & Medicaid Services (CMS) website.

For a complete list of the specific HCPCS codes in the 80000 series that are excluded from CLIA edits, please refer to <http://www.cms.hhs.gov/CLIA/downloads/cpt4exc.pdf> on the CMS website.

CR4321 is the official instruction issued to your carrier regarding changes mentioned in this article, MM4321. CR4321 may be found by going to <http://www.cms.hhs.gov/Transmittals/downloads/R865CP.pdf> on the CMS website.

Please refer to your local carrier if you have questions about this issue. To find the toll free phone number, go to <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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## Appendix A

The HCPCS codes listed in the chart below are new for 2006 and are subject to CLIA edits. The list does not include new HCPCS codes for waived tests or provider-performed procedures. Effective January 1, 2006, 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).

**Table 1: 2006 HCPCS Codes Subject to CLIA Edits**

HCPCS	Modifier	Description
0103T		Holotranscobalamin, quantitative
0111T		Long-chain (C20 – 22) omega-3 fatty acids in red blood cell (RBC) membranes
80195		Sirolimus
82271		Blood, occult, by peroxidase activity (e.g., guaiac), qualitative; other sources
83631		Lactoferrin, fecal; quantitative
83695		Lipoprotein (a)
83700		Lipoprotein, blood; electrophoretic separation and quantitation
83701		Lipoprotein, blood; high resolution fractionation and quantitation of lipoproteins including lipoprotein subclasses when performed (e.g., electrophoresis, ultracentrifugation)
83704		Lipoprotein, blood; quantitation of lipoprotein particle numbers and lipoprotein particle subclasses (e.g., by nuclear magnetic resonance spectroscopy)
83900		Molecular diagnostics; amplification of patient nucleic acid, multiplex, first two nucleic acid sequences
83907		Molecular diagnostics; lysis of cells prior to nucleic acid extraction (e.g., stool specimens, paraffin embedded tissue)
83908		Molecular diagnostics; signal amplification of patient nucleic acid, each nucleic acid sequence
83909		Molecular diagnostics; separation and identification by high resolution technique (e.g., capillary electrophoresis)
83914		Mutation identification by enzymatic ligation or primer extension, single segment, each segment (eg, oligonucleotide ligation assay (OLA), single base chain extension (SBCE), or allele-specific primer extension (ASPE))
86200		Cyclic citrullinated peptide (CCP), antibody
86355		B cells, total count
86357		Natural killer (NK) cells, total count

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HCPCS	Modifier	Description
86367		Stem cells (i.e., CD34), total count
86480		Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response
87209		Smear, primary source with interpretation; complex special stain (e.g., trichrome, iron hemotoxylin) for ova and parasites
88333		Pathology consultation during surgery; cytologic examination (eg, touch prep, squash prep), initial site
88333	TC	Pathology consultation during surgery; cytologic examination (e.g., touch prep, squash prep), initial site
88333	26	Pathology consultation during surgery; cytologic examination (e.g., touch prep, squash prep), initial site
88334		Pathology consultation during surgery; cytologic examination (eg, touch prep, squash prep), each additional site
88334	TC	Pathology consultation during surgery; cytologic examination (e.g., touch prep, squash prep), each additional site
88334	26	Pathology consultation during surgery; cytologic examination (e.g., touch prep, squash prep), each additional site
88384		Array-based evaluation of multiple molecular probes; 11 through 50 probes
88384	TC	Array-based evaluation of multiple molecular probes; 11 through 50 probes
88384	26	Array-based evaluation of multiple molecular probes; 11 through 50 probes
88385		Array-based evaluation of multiple molecular probes; 51 through 250 probes
88385	TC	Array-based evaluation of multiple molecular probes; 51 through 250 probes
88385	26	Array-based evaluation of multiple molecular probes; 51 through 250 probes
88386		Array-based evaluation of multiple molecular probes; 251 through 500 probes
88386	TC	Array-based evaluation of multiple molecular probes; 251 through 500 probes
88386	26	Array-based evaluation of multiple molecular probes; 251 through 500 probes
89049		Caffeine halothane contracture test (CHCT) for malignant hyperthermia susceptibility, including interpretation and report

Effective January 19, 1993, a laboratory that holds a certificate for provider-performed microscopy procedures may perform only waived tests and those tests specified as provider-performed microscopy procedures in the following table, and no others.

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*Table 2: Provider-Performed Microscopy Procedures*

HCPCS Code	Test
Q0111	Wet mounts, including preparations of vaginal, cervical, or skin specimens
Q0112	All potassium hydroxide (KOH) preparations
Q0113	Pinworm examinations
Q0114	Fern test
Q0115	Post-coital direct, qualitative examinations of vaginal or cervical mucous
81015	Urinalysis; microscopic only
81000	Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; non-automated, with microscopy
81001	Urinalysis, by dipstick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; automated, with microscopy (NOTE: May only be used when the lab is using an automated dipstick urinalysis instrument approved as waived.)
81020	Urinalysis; two or three glass test
89055	Fecal leukocyte examination
89190	Nasal smears for eosinophils
G0027	Semen analysis; presence and/or motility of sperm excluding Huhner

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