

CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 865

Department of Health &
Human Services (DHHS)

Centers for Medicare &
Medicaid Services (CMS)

Date: FEBRUARY 17, 2006

Change Request 4321

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

I. SUMMARY OF CHANGES: This instruction informs contractors about the new HCPCS codes, including modifiers, for 2006 that are both subject to CLIA edits and excluded from CLIA edits

NEW/REVISED MATERIAL :

EFFECTIVE DATE : January 01, 2006

IMPLEMENTATION DATE : July 03, 2006

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R = REVISED, N = NEW, D = DELETED – *Only One Per Row.*

R/N/D	Chapter / Section / SubSection / Title
R	16/Table of Contents
R	16/70/3/Verifying CLIA Certification
R	16/70/6/Certificate for Physician- Performed Microscopy Procedures
R	16/70/9/CLIA License or Licensure Exemption

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Recurring Update Notification
Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 865	Date: February 17, 2006	Change Request 4321
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SUBJECT: Healthcare Common Procedure Coding System (HCPCS) Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits

I. GENERAL INFORMATION

A. Background:

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare & Medicaid 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.

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 (eg, red blood cells or platelets), each unit; and
- 87900 - Infectious agent drug susceptibility phenotype prediction using regularly updated genotypic bioinformatics.

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. 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 only a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4) must not be permitted to be paid for these tests.

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 (eg. 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 (eg, electrophoresis, ultracentrifugation)
83704		Lipoprotein, blood; quantitation of lipoprotein particle numbers and lipoprotein particle subclasses (eg, 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 (eg, stool specimens, paraffin embedded tissue)
83908		Molecular diagnostics; signal amplification of patient nucleic acid, each nucleic acid sequence
83909		Molecular diagnostics; separation and indentification by high resolution technique (eg, 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
86367		Stem cells (ie, CD34), total count
86480		Tuberculosis test, cell mediated immunity measurement of gamma interferon antigen response
87209		Smear, primary source with interpretation; complex special stain (eg, 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 (eg, touch prep, squash prep), initial site
88333	26	Pathology consultation during surgery; cytologic examination (eg, 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 (eg, touch prep, squash prep), each additional site
88334	26	Pathology consultation during surgery; cytologic examination (eg, 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

B. Policy:

The CLIA regulations require a facility to be appropriately certified for each test performed. To ensure that Medicare and Medicaid only pay for laboratory tests in a facility with a valid, current CLIA certificate, laboratory claims are currently edited at the CLIA certificate level.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement

"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers			
					F I S S	M C S	V M S	C W F	
4321.1	Contractors shall apply CLIA edits to the HCPCS codes mentioned above as subject to CLIA edits.			X				X	
4321.2	Contractors shall not allow payment for a claim submitted with the HCPCS codes mentioned above as subject to CLIA edits to a provider without valid current CLIA certificate, with a			X				X	

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers			
FI SS	M C S					V M S	C W F		
	CLIA certificate of waiver (certificate type code 2), or with a CLIA certificate for provider-performed microscopy procedures (certificate type code 4).								
4321.3	Contractors shall return a claim as unprocessable if a CLIA number is not submitted on claims by providers for the HCPCS mentioned above as subject to CLIA edits.			X				X	
4321.4	Contractors shall not require a CLIA certificate for claims submitted by facilities for HCPCS codes 86923, 86960, or 87900.			X					
4321.5	Contractors need not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors shall adjust claims brought to their attention.			X					

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers			
FI SS	M C S					V M S	C W F		
4321.6	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider			X					

Requirement Number	Requirements	Responsibility (“X” indicates the columns that apply)							
		F I	R H I	C a r r i e r	D M E R C	Shared System Maintainers			
F I S S	M C S					V M S	C W F		
	education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.								

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: January 1, 2006 Implementation Date: July 3, 2006 Pre-Implementation Contact(s): Kathy Todd (410) 786-3385	No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.
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Post-Implementation Contact(s): Kathy Todd (410) 786-3385	
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***Unless otherwise specified, the effective date is the date of service.**

Attachment

Medicare Claims Processing Manual

Chapter 16 - Laboratory Services

Table of Contents

(Rev. 865, 02-17-06)

Crosswalk to Old Manuals

*70.6 - Certificate for **Provider**-Performed Microscopy Procedures*

70.9 - HCPCS Subject To and Excluded From CLIA Edits

70.3 - Verifying CLIA Certification

(Rev. 865, Issued: 02-17-06; Effective: 01-01-06; Implementation: 07-03-06)

CWF edits Carrier claims to ascertain that the laboratory identified by the CLIA number is certified to perform the test. (CWF uses data supplied from the certification process.) See Chapter 27 for related specifications.

Providers that bill FIs are responsible for verifying CLIA certification prior to ordering laboratory services under arrangement. The survey process validates that these providers have procedures in place to insure that laboratory services are provided by CLIA approved laboratories.

Refer to the Medicare State Operations Manual for information about CLIA license or the CLIA licensure exemptions.

70.6 - Certificate for **Provider-Performed Microscopy Procedures**

(Rev. 865, Issued: 02-17-06; Effective: 01-01-06; Implementation: 07-03-06)

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, as described below, and no others.

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	<i>Urinalysis; microscopic only</i>
81000	<i>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</i>
81001	<i>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.)</i>
81020	<i>Urinalysis; two or three glass test</i>
89055	<i>Fecal leukocyte examination</i>
89190	<i>Nasal smears for eosinophils</i>
G0027	<i>Semen analysis; presence and/or motility of sperm excluding Huhner</i>

70.9 – HCPCS Subject To and Excluded From CLIA Edits

(Rev. 865, Issued: 02-17-06; Effective: 01-01-06; Implementation: 07-03-06)

At this time, all claims submitted for laboratory tests subject to CLIA are edited at the CLIA certificate level. However, the HCPCS codes that are considered a laboratory test under CLIA change each year. The CMS identifies the new HCPCS (non-waived, non-provider-performed procedure) codes, including any modifiers, that are subject to CLIA edits by providing an updated listing of these tests to the Medicare contractors on an annual basis via a Recurring Update Notification. A facility that submits a claim for any test mentioned in the HCPCS codes that are subject to CLIA edits list must have either a valid, current CLIA certificate of registration (certificate type 9), a CLIA certificate of compliance (certificate type 1), or a CLIA certificate of accreditation (certificate type 3).

For a list of the specific HCPCS codes subject to CLIA edits refer to the following Internet site: <http://www.cms.hhs.gov/CLIA/downloads/Subject.to.CLIA.pdf>

In addition, the CMS identifies the new HCPCS codes in the 80000 series that are excluded from CLIA edits by providing an updated listing of these tests to the Medicare contractors on an annual basis via a Recurring Update Notification. No CLIA certificate

is required for a claim submitted for any test mentioned in the HCPCS codes in the 80000 series that are excluded from CLIA edits list.

For a list of the specific HCPCS codes in the 80000 series that are excluded from CLIA edits refer to the following Internet site:

<http://www.cms.hhs.gov/CLIA/downloads/cpt4exc.pdf>