CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2156	**Date: February 11, 2011**
	Change Request 7277

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

I. SUMMARY OF CHANGES: This change request informs contractors about the new HCPCS codes for 2011 that are both subject to CLIA edits and excluded from CLIA edits. This Recurring Update Notification applies to Chapter 16, Section 70.9.

EFFECTIVE DATE: *January 1, 2011
IMPLEMENTATION DATE: April 4, 2011

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
N/A	

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

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

Attachment – Recurring Update Notification

Pub. 100-04	Transmittal: 2156	Date: February 11, 2011	Change Request: 7277

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

EFFECTIVE DATE: **January 1, 2011**

IMPLEMENTATION DATE: April 4, 2011

I. GENERAL INFORMATION

A. Background: The Clinical Laboratory Improvement Amendments (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 HCPCS codes were discontinued on December 31, 2010:

- G0430 – Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure,
- 82926 - Gastric acid, free and total, each specimen,
- 82928 - Gastric acid, free or total, each specimen,
- 86903 - Blood typing; antigen screening for compatible blood unit using reagent serum, per unit screened,
- 89100 - Duodenal intubation and aspiration; single specimen (e.g., simple bile study or afferent loop culture) plus appropriate test procedure,
- 89105 - Duodenal intubation and aspiration; collection of multiple fractional specimens with pancreatic or gallbladder stimulation, single or double lumen tube,
- 89130 - Gastric intubation and aspiration, diagnostic, each specimen, for chemical analyses or cytopathology,
- 89132 - Gastric intubation and aspiration, diagnostic, each specimen, for chemical analyses or cytopathology; after stimulation,
- 89135 - Gastric intubation, aspiration, and fractional collections (e.g., gastric secretory study); one hour,
- 89136 - Gastric intubation, aspiration, and fractional collections (e.g., gastric secretory study); two hours,
- 89140 - Gastric intubation, aspiration, and fractional collections (e.g., gastric secretory study); two hours including gastric stimulation (e.g., histalog, pentagastrin),
- 89141 - Gastric intubation, aspiration, and fractional collections (e.g., gastric secretory study); three hours, including gastric stimulation,

- 89225 - Starch granules, feces, and
- 89235 - Water load test.

The following HCPCS codes are new for 2011, are excluded from CLIA edits and do not require a facility to have any CLIA certificate:

- 88177 – Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, each separate additional evaluation episode, same site (list separately in addition to code for primary procedure and
- 88749 - Unlisted in vivo (e.g., transcutaneous) laboratory service.

Additionally, the HCPCS code 88172 [Cytopathology, evaluation of fine needle aspirate; immediate cytohistologic study to determine adequacy for diagnosis, first evaluation episode, each site] is not subject to CLIA edits and does not required a facility to have any CLIA certificate.

The HCPCS codes listed in the chart that follows are new for 2011 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.

HCPCS	**Description**
G0432	Infectious agent antibody detection by enzyme immunoassay (EIA) technique, HIV-1 and/or HIV-2, screening
G0433	Infectious agent antibody detection by enzyme-linked immunosorbent assay (ELISA) technique, HIV-1 and/or HIV-2, screening
G0434	Drug screen, other than chromatographic; any number of drug classes, by CLIA waived test or moderate complexity test, per patient encounter
G0435	Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening
G9143	Warfarin responsiveness testing by genetic technique using any method, any number of specimens
82930	Gastric acid analysis, includes pH if performed, each specimen
83861	Microfluidic analysis utilizing an integrated collection and analysis device; tear osmolarity
84112	Placental alpha microglobulin-1 (PAMG-1), cervicovaginal secretion, qualitative
85598	Phospholipid neutralization; hexagonal phospholipid
86481	Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon producing T-cells in cell suspension
86902	Blood typing; antigen testing of donor blood using reagent serum, each antigen test
87501	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, reverse transcription and amplified probe technique, each type or subtype
87502	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus,

	for multiple types or sub-types, reverse transcription and amplified probe technique, first 2 types or sub-types
87503	Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, multiplex for multiple types or sub-types, multiplex reverse transcription and amplified probe technique, each additional influenza virus type or sub-type beyond 2 (List separately in addition to code for primary procedure)
87906	Infectious agent genotype analysis by nucleic acid (DNA or RNA); HIV-1, other region (e.g., integrase, fusion)
88120	Cytopathology, in situ hybridization (e.g., FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; manual
88121	Cytopathology, in situ hybridization (e.g., FISH), urinary tract specimen with morphometric analysis, 3-5 molecular probes, each specimen; using computer-assisted technology
88363	Examination and selection of retrieved archival (i.e., previously diagnosed) tissue(s) for molecular analysis (e.g., kras mutational analysis)

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

Use "Shall" to denote a mandatory requirement

Number	**Requirement**	**Responsibility (place an "X" in each applicable column)**										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
7277.1	Contractors shall apply CLIA edits to the HCPCS codes mentioned above as subject to CLIA edits.	X			X						X	
7277.2	Contractors shall deny 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 CLIA certificate of waiver (certificate type code 2), or with a CLIA certificate for provider-performed microscopy procedures (certificate type code 4).	X			X							
7277.3	Contractors shall return a claim as	X			X							

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	unprocessable if a CLIA number is not submitted on claims by providers for the HCPCS mentioned above as subject to CLIA edits.											
7277.4	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			X							

III. PROVIDER EDUCATION

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
7277.5	A provider education article related to this instruction will be available at www.cms.hhs.gov/MLNMattersArticles shortly after the CR is released. You will receive notification of the article release via the established "MLN 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 one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly	X			X							

Number	Requirement	Responsibility (place an "X" in each applicable column)										
		A/B MAC	DME MAC	FI	CARRIER	DMERC	RHHI	Shared-System Maintainers				OTHER
								FISS	MCS	VMS	CWF	
	scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.											

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
N/A	

B. For all other recommendations and supporting information, use the space below:

V. CONTACTS

Pre-Implementation Contact(s): Kathy Todd (410) 786-3385

Post-Implementation Contact(s): Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

VI. FUNDING

A. ***For Fiscal Intermediaries (FIs) and Carriers*****:**

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

B. ***For Medicare Administrative Contractors (MAC)*****:**

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts specified in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.