

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-20 One-Time Notification	Centers for Medicare & Medicaid Services (CMS)
Transmittal 720	Date: June 18, 2010
	Change Request 6985

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

I. SUMMARY OF CHANGES: This change request informs contractors about additional new HCPCS codes for 2010 that are subject to CLIA edits. This Recurring Update Notification applies to Chapter 16, Section 70.9.

EFFECTIVE DATE: January 1, 2009

IMPLEMENTATION DATE: July 19, 2010

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/revise 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:

One-Time Notification

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

Attachment – One-Time Notification

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

EFFECTIVE DATE: January 1, 2009

IMPLEMENTATION DATE: July 19, 2010

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 and 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 listed in the chart that follows were new in 2009, are subject to CLIA edits and were not mentioned in CR 6812 [Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits] or CR 6356. 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	Modifier	Description
G0416		Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 1-20 specimens
G0416	TC	Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 1-20 specimens
G0416	26	Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 1-20 specimens
G0417		Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 21-40 specimens
G0417	TC	Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 21-40 specimens
G0417	26	Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 21-40 specimens
G0418		Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41-60 specimens
G0418	TC	Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41-60 specimens
G0418	26	Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, 41-60 specimens
G0419		Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens
G0419	TC	Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens

G0419	26	Surgical pathology, gross and microscopic examination for prostate needle saturation biopsy sampling, greater than 60 specimens
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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 TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M A A C	F I I E R	C A R I E R	R H H I E S	Shared-System Maintainers				OTH ER
						F I S S	M C S	V M S	C W F		
6985.1	Contractors shall apply CLIA edits to the HCPCS codes mentioned above as subject to CLIA edits.	X			X						
6985.2	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						
6985.3	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						
6985.4	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 TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M A A C	F I I E R	C A R I E R	R H H I E S	Shared-System Maintainers				OTH ER
						F I S S	M C S	V M S	C W F		
6985.5	A provider education article related to this instruction will be available at www.cms.hhs.gov/MLN MattersArticles shortly after the CR is released. You will receive notification of the article release via the established	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / B M A C	D M E M A C	F I M A C	C A R I E R	R H H I	Shared-System Maintainers			
						F I S S	M C S	V M S	C W F	
	"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 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

Section 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	

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

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

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

VI. FUNDING

Section A: 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.

Section B: For *Medicare Administrative Contractors (MACs)*, include the following statement:

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.