CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 1165	<b>Date: JANUARY 26, 2007</b>
	Change Request 5457

SUBJECT: Healthcare 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 for 2007 that are both subject to and excluded from CLIA edits.

**NEW / REVISED MATERIAL** 

EFFECTIVE DATE: \*January 1, 2007 IMPLEMENTATION DATE: April 2, 2007

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:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2007 operating budgets.

#### **IV. ATTACHMENTS:**

### **Recurring Update Notification**

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

## **Attachment – Recurring Update Notification**

Pub. 100-04 | Transmittal: 1165 | Date: January 26, 2007 | Change Request 5457

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

Effective Date: January 1, 2007

**Implementation Date:** April 2, 2007

#### 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 for Mohs micrographic surgery were discontinued on 12/31/2006:

- 17304 Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histological preparation including the first routine stain (eg, hematoxylin and eosin, toluidine blue); first stage, fresh tissue technique, up to five specimens;
- 17305 Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histological preparation including the first routine stain (eg, hematoxylin and eosin, toluidine blue); second stage, fixed or fresh tissue technique, up to five specimens;
- 17306 Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histological preparation including the first routine stain (eg, hematoxylin and eosin, toluidine blue); third stage, fixed or fresh tissue technique, up to five specimens;
- 17307 Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and complete histological preparation including the first routine stain (eg, hematoxylin and eosin, toluidine blue); additional stage(s), up to five specimens, each stage; and
- 17310 Chemosurgery (Mohs micrographic technique), including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic

examination of specimens by the surgeon, and complete histological preparation including the first routine stain (eg, hematoxylin and eosin, toluidine blue); each additional specimen, after the first five specimens, fixed or fresh tissue any stage (list separately in addition to code for primary procedure).

The HCPCS codes listed in the chart below are new for 2007 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	Modifier	Description
17311		Mohs micrographic technique, including removal of all
		gross tumor, surgical excision of tissue specimens, mapping,
		color coding of specimens, microscopic examination of
		specimens by the surgeon, and histopathologic preparation
		including routine stain(s) (eg, hematoxylin and eosin,
		toluidine blue), head, neck, hands, feet, genitalia, or any
		location with surgery directly involving muscle, cartilage,
		bone, tendon, major nerves, or vessels; first stage, up to 5
		tissue blocks
17312		Mohs micrographic technique, including removal of all
		gross tumor, surgical excision of tissue specimens, mapping,
		color coding of specimens, microscopic examination of
		specimens by the surgeon, and histopathologic preparation
		including routine stain(s) (eg, hematoxylin and eosin,
		toluidine blue), head, neck, hands, feet, genitalia, or any
		location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; each additional stage
		after the first stage, up to 5 tissue blocks (List separately in
		addition to code for primary procedure)
17313		Mohs micrographic technique, including removal of all
17313		gross tumor, surgical excision of tissue specimens, mapping,
		color coding of specimens, microscopic examination of
		specimens by the surgeon, and histopathologic preparation
		including routine stain(s) (eg, hematoxylin and eosin,
		toluidine blue), of the trunk, arms, or legs; first stage, up to
		5 tissue blocks
17314		Mohs micrographic technique, including removal of all
		gross tumor, surgical excision of tissue specimens, mapping,
		color coding of specimens, microscopic examination of
		specimens by the surgeon, and histopathologic preparation
		including routine stain(s) (eg, hematoxylin and eosin,
		toluidine blue), of the trunk, arms, or legs; each additional

	stage often the first stage, up to 5 tissue blocks (List
	stage after the first stage, up to 5 tissue blocks (List
	separately in addition to code for primary procedure)
17315	Mohs micrographic technique, including removal of all
	gross tumor, surgical excision of tissue specimens, mapping,
	color coding of specimens, microscopic examination of
	specimens by the surgeon, and histopathologic preparation
	including routine stain(s) (eg, hematoxylin and eosin,
	toluidine blue), each additional block after the first 5 tissue
	blocks, any stage (List separately in addition to code for
	primary procedure)
82107	Alpha-fetoprotein (AFP); AFP-L3 fraction isoform and total
	AFP (including ratio)
83698	Lipoprotein-associated phospholipase A <sub>2</sub> , (Lp-PLA <sub>2</sub> )
83913	Molecular diagnostics; RNA stabilization
86788	Antibody; West Nile virus, IgM
86789	Antibody; West Nile virus
87305	Infectious agent antigen detection by enzyme immunoassay
	technique, qualitative or semiquantitative, multiple-step
	method; Aspergillus
87498	Infectious agent detection by nucleic acid (DNA or RNA);
	enterovirus, amplified probe technique
87640	Infectious agent detection by nucleic acid (DNA or RNA);
	Staphylococcus aureus, amplified probe technique
87641	Infectious agent detection by nucleic acid (DNA or RNA);
	Staphylococcus aureus, methicillin resistant, amplified
	probe technique
87653	Infectious agent detection by nucleic acid (DNA or RNA);
	Streptococcus, group B, amplified probe technique
87808	Infectious agent detection by immunoassay with direct
	optical observation; Trichomonas vaginalis
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Additionally, even though HCPCS codes are not currently edited at the laboratory certification (LC) level, the LC code of 610 for the specialty of histopathology needs to be added to the new Mohs (i.e., 17311, 17312, 17313, 17314, and 17315).

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	D M E	F I	C A R	D M E	R H H	Sy: Ma	ared- stem	iners	ı	OTHER
		M A C	M A C		R I E R	R C	I	F I S S	M C S	V M S	C W F	
5457.1	CWF shall add the laboratory certification (LC) code of 610 to the HCPCS codes 17311, 17312, 17313, 17314, and 17315. CWF shall not edit for the LC code.										X	
5457.2	Contractors shall apply CLIA edits to the HCPCS codes mentioned above as subject to CLIA edits.	X			X						X	
5457.3	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						X	
5457.4	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						X	
5457.5	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			X							

### III. PROVIDER EDUCATION

Numbe	Requirement	Responsibility (place an "X" in each										
r		applicable column)										
		Α	D	F	С	D	R	Sh	ared-	Syst	em	OTHER
		/	M	I	Α	M	Н	Ma	intai	iners		
		BERREH						F	M	V	С	
					R	R	I	I	C	M	W	
		M	M		Ι	C		S	S	S	F	
		Α	A		Е			S				
		C	C		R							

Numbe	Responsibility (place an "X" in each					ach						
r		applicable column)										
		A / B	D M E	F I	C A R	D M E	R H H	Ma	inta	Syst		OTHER
		M A C	M A C		R I E R	R C	I	F I S S	M C S	V M S	C W F	
5457.6	A provider education article related to this instruction will be available at <a href="https://www.cms.hhs.gov/MLNMattersArticles">www.cms.hhs.gov/MLNMattersArticles</a> 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 1 week of the availability of the provider 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 MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X			X							

### 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	Recommendations or other supporting information:
Requirement	
Number	

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):** Kathy Todd (410) 786-3385

### VI. FUNDING

### **A.** For TITLE XVIII Contractors, use only one of the following statements:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

### **B.** For Medicare Administrative Contractors (MAC), use only one of the following statements:

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.