CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2857	**Date: January 17, 2014**
	Change Request 8567

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 2014 that are both subject to and excluded from CLIA edits. This Recurring Update Notification applies to Chapter 16, section 70.9.

EFFECTIVE DATE: January 1, 2014
IMPLEMENTATION DATE: April 7, 2014

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 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 obliged 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: 2857	Date: January 17 2014	Change Request: 8567

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

EFFECTIVE DATE: January 1, 2014
IMPLEMENTATION DATE: April 7, 2014

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 HCPCS codes listed below are new for 2014 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.

- G0461 - Immunohistochemistry or immunocytochemistry, per specimen; first single or multiplex antibody stain;
- G0462 - Immunohistochemistry or immunocytochemistry, per specimen; each additional single or multiplex antibody stain (list separately in addition to code for primary procedure);
- 80155 - Caffeine level;
- 80159 - Clozapine level;
- 80169 - Everolimus level;
- 80171 - Gabapentin level;
- 80175 - Lamotrigine level;
- 80177 - Levetiracetam level;
- 80180 - Mycophenolate (mycophenolic acid) level;
- 80183 - Oxcarbazepine level;
- 80199 - Tiagabine level;
- 80203 - Zonisamide level;

- 81287 - MGMT (O-6-methylguanine-DNA methyltransferase) gene analysis;
- 81504 - Genetic profiling on oncology biopsy lesions;
- 81507 - DNA analysis using maternal plasma; and
- 87661 - Infectious agent detection by nucleic acid (dna or rna); trichomonas vaginalis, amplified probe technique.

Additionally, for 2014, there was 1 new HCPCS code for immunohistochemistry or immunocytochemistry [i.e., 88343 - Immunohistochemistry or immunocytochemistry, each separately identifiable antibody per block, cytologic preparation, or hematologic smear; each additional separately identifiable antibody per slide (list separately in addition to code for primary procedure)]. The testing described by this code is subject to the CLIA regulations, however, it is not payable by Medicare in CY 2014. Hence, this new code was not included in this Change Request.

This Recurring Update Notification applies to Chapter 16, Section 70.9.

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

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
8567.1	Contractors shall apply CLIA edits to the HCPCS codes mentioned above as subject to CLIA edits.		X						X	
8567.2	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							
8567.3	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							
8567.4	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							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
8567.5	MLN Article : A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/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 sites 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 the contractor's 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.		X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Kathleen Todd, 410-786-3385 or kathleen.todd@cms.hhs.gov

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS do 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.