



News Flash – The revised “Clinical Laboratory Fee Schedule Fact Sheet” (January 2010), which provides general information about the Clinical Laboratory Fee Schedule, coverage of clinical laboratory services, and how payment rates are set, is now available in print format from the Centers for Medicare & Medicaid Services Medicare Learning Network. To place your order, visit <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/index.html>, scroll down to “Related Links Inside CMS” and select “MLN Product Ordering Page.”

MLN Matters® Number: MM6985 **Revised**

Related Change Request (CR) #: 6985

Related CR Release Date: June 18, 2010

Effective Date: January 1, 2009

Related CR Transmittal #: R7200TN

Implementation Date: July 19, 2010

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

Note: This article was updated on December 6, 2012, to reflect current Web addresses. This article was previously revised on May 17, 2011 to add a reference to MLN Matters® article MM7325 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM7325.pdf>), which reiterates the policy that states that no CLIA certificate is required for a claim submitted for any test mentioned in the HCPCS 80000 series codes that are excluded from the CLIA edits list. Contractors must ensure that codes on this list are not subject to CLIA edits. All other information is the same.

Provider Types Affected

Clinical Laboratories submitting claims to Medicare Part A/B Medicare Administrative Contractors (A/B MACs) or carriers for laboratory services provided to Medicare beneficiaries are impacted by this issue.

What You Need to Know

Change Request (CR) 6985, from which this article is taken, informs your A/B MAC or carrier about additional new Healthcare Common Procedure Coding System (HCPCS) codes for 2010 that are subject to Clinical Laboratory

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Improvement Amendments (CLIA) edits. You should make sure that your billing staff is aware of the changes.

Background

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 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.

Since the HCPCS codes that are considered a laboratory test under CLIA change each year, the Center for Medicare & Medicaid Services (CMS) informs carriers and MACs about the new HCPCS codes that are subject to, and those that are excluded from, CLIA edits. CR 6985, from which this article is taken, announces additional HCPCS codes that are subject to CLIA edits for 2009~~10~~, but were not mentioned in CR 6812 or CR 6356.

Note: Please refer to MLN Matters® article MM6812 (Healthcare Common Procedure Coding System (HCPCS) Codes Subject to and Excluded from Clinical Laboratory Improvement Amendments (CLIA) Edits), released February 5, 2010; which you can find at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6812.pdf> on the CMS website.

The HCPCS codes listed in the table, below, are new for 2009 and subject to CLIA edits, and 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 a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4) cannot 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

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HCPCS	Modifier	Description
		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

Please note that your carrier or MAC is not required to search their files to either retract payment for claims already paid or to retroactively pay claims containing these codes, but will adjust such claims that you bring to their attention.

Additional Information

You can find the official instruction, CR6985, issued to your carrier or A/B MAC by visiting <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R7200TN.pdf> on the CMS website.

If you have any questions, please contact your carrier or A/B MAC at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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