CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3182	**Date: January 30, 2015**
	Change Request 9035

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 2015 that are subject to and excluded from CLIA edits. This Recurring Update Notification applies to Chapter 16, section 70.9.

EFFECTIVE DATE: January 1, 2015
Unless otherwise specified, the effective date is the date of service.
IMPLEMENTATION DATE: April 6, 2015

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

Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 3182	Date: January 30, 2015	Change Request: 9035

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

EFFECTIVE DATE: January 1, 2015
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IMPLEMENTATION DATE: April 6, 2015

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, 2014:

- G0417- Surgical pathology, gross and microscopic examination, for prostate needle biopsy, any method, 21-40 specimens;

- G0418 - Surgical pathology, gross and microscopic examination, for prostate needle biopsy, any method, 41-60 specimens;

- G0419 - Surgical pathology, gross and microscopic examination, for prostate needle biopsy, any method, >60 specimens;

- 80100 - Drug screen, multiple drugs;

- 80101 - Drug screen;

- 80102 - Drug confirmation test;

- 80103 - Tissue preparation for drug analysis;

- 80104 - Drug screen, multiple drugs;

- 80152 - Amitriptyline (antidepressant) level;

- 80154 - Benzodiazepines level;

- 80160 - Desipramine level;

- 80166 - Assay of doxepin;

- 80172 - Gold level;

- 80174 - Imipramine level;

- 80182 - Nortriptyline level;

- 80196 - Salicylate (aspirin) level;

- 80440 - Thyrotropin releasing hormone (TRH) (hypothalamus hormone) stimulation panel;

- 82000 - Acetaldehyde blood test;

- 82003 - Acetaminophen level;

- 82055 - Alcohol (ethanol) level;

- 82101 - Urine alkaloids level;

- 82145 - Amphetamine or methamphetamine level;

- 82205 - Barbiturates level;

- 82520 - Cocaine (drug) level;

- 82646- Dihydrocodeinone (drug) measurement;

- 82649 - Dihydromorphinone (drug) level;

- 82651 - Dihydrotestosterone (DHT) level;

- 82654 - Dimethadione (drug) level;

- 82666 - Epiandrosterone (synthetic hormone) level;

- 82690 - Ethchlorvynol (drug) level;

- 82742 - Flurazepam (drug) level;

- 82953 - Glucose (sugar) tolerance test;

- 82975 - Glutamine (amino acid by product) level;

- 82980 - Glutethimide (drug) level;

- 83008 - Guanosine monophosphate (cellular chemical) level;

- 83055 - Sulfhemoglobin (hemoglobin) analysis;

- 83071 - Hemosiderin (hemoglobin breakdown product) level;

- 83634 - Urine lactose (carbohydrate) analysis;

- 83805 - Meprobamate (sedative) level;

- 83840 - Methadone level;

- 83858 - Methsuximide (drug) level;

- 83866 - Mucopolysaccharides (protein) screening test;

- 83887 - Nicotine level;

- 83925 - Opiates (drug) measurement;

- 84022 - Phenothiazine (drug) level;

- 84127 - Stool porphyrins (metabolism substance) analysis;

- 87001 - Animal inoculation, small animal with observation;

- 87620 - Detection test for human papillomavirus (HPV);

- 87621 - Detection test for human papillomavirus (HPV);

- 87622 - Detection test for human papillomavirus (HPV);

- 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); and

- 88349 - Assessment using electron microscopy.

The HCPCS code 89337 [Frozen preservation of mature eggs] is new for 2015, is excluded from CLIA edits and does not require a facility to have any CLIA certificate.

The HCPCS codes listed below are new for 2015 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.

- G0464 - Colorectal cancer screening; stool-based dna and fecal occult hemoglobin (e.g., kras, ndrg4 and bmp3)

- G6030 – Amitriptyline;

- G6031- Benzodiazepines;

- G6032 – Desipramine;

- G6034 – Doxepin;

- G6035 – Gold;

- G6036 – Assay of imipramine;

- G6037 – Nortriptyline;

- G6038 – Salicylate;

- G6039 – Acetaminophen;

- G6040 – Alcohol (ethanol); any specimen except breath;

- G6041 – Alkaloids, urine, quantitative;

- G6042 – Amphetamine or methamphetamine;

- G6043 – Barbiturates, not elsewhere specified;

- G6044 – Cocaine or metabolite;

- G6045 – Dihydrocodeinone;

- G6046 – Dihydromorphinone;

- G6047 – Dihydrotestosterone;

- G6048 – Dimethadione;

- G6049 – Epiandrosterone;

- G6050 – Ethchlorvynol;

- G6051 – Flurazepam;

- G6052 – Meprobamate;

- G6053 – Methadone;

- G6054 – Methsuximide;

- G6055 – Nicotine;

- G6056 – Opiate(s), drug and metabolites, each procedure;

- G6057 - Phenothiazine;

- G6058 - Drug confirmation, each procedure;

- 80163 - Digoxin level;

- 80165 - Valproic acid level;

- 80300 - Drug screen;

- 80301 - Drug screen;

- 80302 - Drug screen;

- 80303 - Drug screen;

- 80304 - Drug screen;

- 80320 - Alcohols levels;

- 80321 - Alcohols levels;

- 80322 - Alcohols levels;

- 80323 - Alkaloids levels;

- 80324 - Amphetamines levels;

- 80325 - Amphetamines levels;

- 80326 - Amphetamines levels;

- 80327 - Anabolic steroids levels

- 80328 - Anabolic steroids levels

- 80329 - Analgesics levels;

- 80330 - Analgesics levels;

- 80331 - Analgesics levels;

- 80332 - Antidepressants levels;

- 80333 – Antidepressants levels;

- 80334 – Antidepressants levels;

- 80335 – Antidepressants levels

- 80336 – Antidepressants levels;

- 80337 - Antidepressants levels;

- 80338 – Antidepressants levels;

- 80339 - Antiepileptics levels;

- 80340 – Antiepileptics levels;

- 80341 – Antiepileptics levels;

- 80342 – Antipsychotics levels;

- 80343 – Antipsychotics levels;

- 80344 – Antipsychotics levels;

- 80345 – Barbiturates levels;

- 80346 - Benzodiazepines levels;

- 80347 – Benzodiazepines levels;

- 80348 – Buprenorphine level

- 80349 – Cannabinoids levels

- 80350 - Cannabinoids levels

- 80351 - Cannabinoids levels;

- 80352 - Cannabinoids levels;

- 80353 – Cocaine level;

- 80354 – Fentanyl level;

- 80355 – Gabapentin level non-blood;

- 80356 – Heroin metabolite level;

- 80357 – Ketamine and norketamine levels;

- 80358 – Methadone level;

- 80359 – Methylenedioxyamphetamines levels;

- 80360 – Methylphenidate level;

- 80361 – Opiates levels;

- 80362 – Opioids levels;

- 80363 – Opioids levels;

- 80364 – Opioids levels;

- 80365 – Oxycodone levels;

- 80366 – Pregabalin level;

- 80367 – Propoxyphene level;

- 80368 – Sedative hypnotics (non-benzodiazepines) levels

- 80369 – Skeletal muscle relaxants levels;

- 80370 – Skeletal muscle relaxants levels;

- 80371 – Synthetic stimulants levels;

- 80372 – Tapentadol level;

- 80373 – Tramadol level;

- 80374 – Stereoisomer (enantiomer) drug analysis;

- 80375 – Drugs or substances measurement;

- 80376 – Drugs or substances measurement;

- 80377 - Drugs or substances measurement;

- 81246 - Test for detecting genes associated with blood cancer;

- 81288 - Test for detecting genes associated with colon cancer;

- 81313 - Test for detecting genes associated with prostate cancer;

- 81410 - Test for detecting genes associated with heart disease;

- 81411 - Test for detecting genes associated with heart disease;

- 81415 - Test for detecting genes associated with diseases;

- 81416 - Test for detecting genes associated with disease;

- 81417 - Reevaluation test for detecting genes associated with disease;

- 81420 - Test for detecting genes associated with fetal disease;

- 81425 - Test for detecting genes associated with disease;

- 81426 - Test for detecting genes associated with disease;

- 81427 - Reevaluation test for detecting genes associated with disease;

- 81430 - Test for detecting genes causing hearing loss;

- 81431 - Test for detecting genes causing hearing loss;

- 81435 - Test for detecting genes associated with colon cancer;

- 81436 - Test for detecting genes associated with colon cancer;

- 81440 - Test for detecting genes associated with cancer of body organ;

- 81445 - Test for detecting genes associated with cancer of body organ;

- 81450 - Test for detecting genes associated with blood related cancer;

- 81455 - Test for detecting genes associated with cancer;

- 81460 - Test for detecting genes associated with disease;

- 81465 - Test for detecting genes associated with disease;

- 81470 - Test for detecting genes associated with intellectual disability;

- 81471 - Test for detecting genes associated with intellectual disability;

- 81519 - Test for detecting genes associated with breast cancer;

- 83006 - Test for detecting genes associated with growth stimulation;

- 87505 - Detection test for digestive tract pathogen;

- 87506 - Detection test for digestive tract pathogen;

- 87507 - Detection test for digestive tract pathogen;

- 87623 - Detection test for human papillomavirus (hpv);

- 87624 - Detection test for human papillomavirus (hpv);

- 87625 - Detection test for human papillomavirus (hpv);

- 87806 - Detection test for HIV-1;

- 88341 - Special stained specimen slides to examine tissue;

- 88344 - Special stained specimen slides to examine tissue;

- 88364 - Cell examination;

- 88366 - Cell examination;

- 88369 - Microscopic genetic examination manual;

- 88373 - Microscopic genetic examination using computer-assisted technology;

- 88374 - Microscopic genetic examination using computer-assisted technology; and

- 88377 - Microscopic genetic examination manual.

Additionally, Change Request 8871 mentioned that effective for services performed on or after June 2, 2014, the new HCPCS G0472, HCV screening, will be recognized as a covered service. G0472 is a code that is considered a test under CLIA; is subject to CLIA edits; and would 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).

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			D M E MAC	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
9035.1	Contractors shall apply CLIA edits to the HCPCS codes mentioned above as subject to CLIA edits.		X						X	
9035.2	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							
9035.3	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							
9035.4	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			D M E MAC	C E D I
		A	B	H H H		
9035.5	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		X			

Number	Requirement	Responsibility				
		A/B MAC			D M E M A C	C E D I
		A	B	H H H		
	administering the Medicare program correctly.					

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).

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 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.

ATTACHMENTS: 0