CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3439	**Date: January 15, 2016**
	Change Request 9502

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 2016 that are subject to and excluded from CLIA edits. This Recurring Update Notification applies to Chapter 16, section 70.9.

EFFECTIVE DATE: January 1, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 4, 2016

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 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:
Recurring Update Notification

Attachment - Recurring Update Notification

Pub. 100-04	Transmittal: 3439	Date: January 15, 2016	Change Request: 9502

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

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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, 2015:

- G0431- Drug screen, qualitative; multiple drug classes by high complexity test method (e.g., immunoassay, enzyme assay), per patient encounter;
- G0434 - Drug screen, other than chromatographic; any number of drug classes, by clia waived test or moderate complexity test, per patient encounter;
- 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;
- 82486 – Chemical analysis;
- 82487 – Chemical analysis;
- 82488 – Chemical analysis;
- 82489 – Chemical analysis;
- 82491 – Chemical analysis;
- 82492 – Chemical analysis;
- 82541 – Chemical analysis using chromatography technique;
- 82543 – Chemical analysis using chromatography technique:
- 82544 - Chemical analysis using chromatography technique;
- 83788 - Mass spectrometry (laboratory testing method;
- 88347 - Antibody evaluation; and

- 0103T - Measurement of vitamin B-12 deficiency marker.

The HCPCS codes listed below are new for 2016 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.

- G0477 - Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg immunoassay) capable of being read by direct optical observation only (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service;

- G0478 – Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures, (eg immunoassay) read by instrument-assisted direct optical observation (eg, dipsticks, cups, cards, cartridges), includes sample validation when performed, per date of service;

- G0479 – Drug tests(s), presumptive, any number of drug classes; any number of devices or procedures by instrumented chemistry analyzers utilizing immunoassay, enzyme assay, TOF, MALDI, LDTD, DESI, DART, GHPC, GC mass spectrometry), includes sample validation when performed, per date of service;

- G0480 – Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 1-7 drug class(es), including metabolite(s) if performed;

- G0481 – Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 8-14 drug class(es), including metabolite(s) if performed;

- G0482 – Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 15-21 drug class(es), including metabolite(s) if performed;

- G0483 – Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (eg, IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (eg, alcohol dehydrogenase)); qualitative or quantitative, all sources(s), includes specimen validity testing, per day, 22 or more drug class(es), including metabolite(s) if performed

- 80081 - Blood test panel for obstetrics (cbc, differential wbc count, hepatitis b, hiv, rubella, syphilis, antibody screening, rbc, blood typing);

- 81162 - Gene analysis (breast cancer 1 and 2) full sequence and duplication or deletion variants;
- 81170 - Gene analysis (ABL proto-oncogene 1, non-receptor tyrosine kinase);
- 81218 - Gene analysis (ccaat/enhancer binding protein [c/ebp], alpha) full gene sequence;
- 81219 - Gene analysis (calreticulin), common variants;
- 81272 - Gene analysis (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog), targeted sequence;
- 81273 - Gene analysis (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog), D816 variants;
- 81276 - Gene analysis (Kirsten rat sarcoma viral oncogene homolog), additional variants;
- 81311 - Gene analysis for cancer (neuroblastoma);
- 81314 - Gene analysis ((platelet-derived growth factor receptor, alpha polypeptide) targeted sequence;
- 81412 - Test for detecting genes for disorders related to Ashkenazi Jews;
- 81432 - Gene analysis (breast and related cancers), genomic sequence;
- 81433 – Gene analysis (breast and related cancers), duplication or deletion variants
- 81434 - Gene analysis (retinal disorders), genomic sequence;
- 81437 - Gene analysis (neuroendocrine tumors), genomic sequence;
- 81438 - Gene analysis (neuroendocrine tumors), duplication and deletion variants;
- 81442 - Gene analysis (noonan syndrome) genomic sequence analysis;
- 81490 – Test for detecting genes associated with rheumatoid arthritis using immunoassay technique;
- 81493 - Test for detecting genes associated with heart vessels diseases;
- 81525 - Gene analysis (colon related cancer;
- 81528 - Gene analysis (colorectal cancer);
- 81535 - Culture of live tumor cells and chemotherapy drug response by staining;
- 81536 - Culture of live tumor cells and chemotherapy drug response by staining;
- 81538 - Testing of lung tumor cells for prediction of survival;
- 81540 - Gene analysis (cancer);
- 81545 - Gene analysis (thyroid cancer);
- 81595 - Test for detecting genes associated with heart diseases;

- 88350 - Antibody evaluation;

- 0009M - Fetal aneuploidy (trisomy 21, and 18) dna sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy; and

- 0010M - Oncology (high-grade prostate cancer), biochemical assay of four proteins (total psa, free psa, intact psa and human kallidrein 2 (hk2)) plus patient age, digital rectal examination status, and no history of positive prostate biopsy, utilizing plasma, prognostic algorithm reported as a probability score.

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	
9502.1	Contractors shall apply CLIA edits to the HCPCS codes mentioned above as subject to CLIA edits.		X						X	
9502.2	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							
9502.3	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							
9502.4	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		
9502.5	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 5 business days after receipt of the notification from CMS announcing the availability of the 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:

"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