

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



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

Provider Types Affected

This MLN Matters® Article is intended for clinical diagnostic laboratories submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9502 informs MACs about the Healthcare Common Procedure Coding System (HCPCS) codes for 2016 that are both subject to, and excluded from, CLIA edits; and also includes the HCPCS codes discontinued as of December 31, 2015. Make sure that your billing staffs are aware of these CLIA-related changes for 2016.

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.

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Discontinued HCPCS Codes

The HCPCS codes listed in table 1 below were discontinued on December 31, 2015

Table 1: HCPCS Codes Discontinued on December 31, 2015

| HCPCS Code | Descriptor |
|-------------------|---|
| 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 |

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| HCPCS Code | Descriptor |
|-------------------|--|
| 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 |
| 0103T | Measurement of vitamin B-12 deficiency marker |

New HCPCS Codes for 2016

The HCPCS codes listed in table 2, 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:

1. CLIA certificate of registration (certificate type code 9);
2. CLIA certificate of compliance (certificate type code 1); or
3. CLIA certificate of accreditation (certificate type code 3).

The following facilities are not permitted to be paid for these tests:

1. A facility without a valid, current, CLIA certificate;
2. A facility with a current CLIA certificate of waiver (certificate type code 2); or
3. A facility with a current CLIA certificate for provider-performed microscopy procedures (certificate type code 4).

Table 2: New HCPCS Codes Subject to CLIA Edits for 2016

| HCPCS Code | Descriptor |
|-------------------|---|
| 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 |

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| HCPCS Code | Descriptor |
|------------|--|
| 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 |

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| HCPCS Code | Descriptor |
|-------------------|--|
| 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 |
| 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 |

MACs will not search their files to either retract payment for claims already paid or retroactively pay claims, but will adjust claims that brought to their attention.

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Additional Information

The official instruction, CR 9502 issued to your MAC regarding this change is available at <http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3439CP.pdf> on the CMS website.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - How Does It Work.

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