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

MLN Matters Number: MM11135 | Related Change Request (CR) Number: 11135
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PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for physicians, providers, and suppliers billing Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR11135 informs providers and MACs about the new HCPCS codes for 2019 that are subject to and excluded from Clinical Laboratory Improvement Amendments (CLIA) edits. Make sure your billing staffs are aware of these updates.

BACKGROUND

The HCPCS codes that are considered a laboratory test under CLIA change each year. The following HCPCS codes were discontinued on December 31, 2017:

- 0004U - Test for detecting genes associated with antibiotic resistance in bacterial culture
- 0015U - Test for detecting genes associated with drug metabolism in blood or cheek swab.

The following HCPCS codes were discontinued on September 30, 2018:

- 0020U - Testing for presence of drug in urine with confirmation of positive results and specimen verification
- 0028U, Gene analysis (cytochrome P450, family 2, subfamily D, polypeptide 6) for copy number variants and common variants with follow-up targeted sequence analysis

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The following HCPCS codes were discontinued on December 31, 2018:

- 78270 - Vitamin B-12 absorption study
- 78271 - Vitamin B-12 absorption study with factor necessary for absorption
- 78272 - Vitamin B-12 absorption study without then with factor necessary for absorption
- 81211 - Gene analysis (breast cancer 1 and 2) full sequence and common duplication or deletion variants
- 81213 - Gene analysis (breast cancer 1 and 2) uncommon duplication or deletion variants
- 81214 - Gene analysis (breast cancer 1) full sequence and common duplication or deletion variants

The following HCPCS codes are excluded from CLIA edits, and do not require a facility to have any CLIA certificate:

- 0061U - Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin – Effective July 1, 2018; and
- 0079U - Comparative Deoxyribonucleic Acid (DNA) analysis using multiple selected Single-Nucleotide Polymorphisms (SNPs), urine and buccal DNA, for specimen identity verification – Effective October 1, 2018.

The HCPCS codes listed below were added on October 1, 2017, were not mentioned in a previous transmittal, and are subject to CLIA edits. 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.

- 0018U - Oncology (thyroid), microRNA profiling by RT-PCR of 10 microRNA sequences, utilizing fine needle aspirate, algorithm reported as a positive or negative result for moderate to high risk of malignancy A3;
- 0019U - Oncology, RNA, gene expression by whole transcriptome sequencing, formalin-fixed paraffin embedded tissue or fresh frozen tissue, predictive algorithm reported as potential targets for therapeutic agents;
- 0021U - Oncology (prostate), detection of 8 autoantibodies (ARF 6, NKX3-1, 5'-UTR-BMI1, CEP 164, 3'-UTR-Ropporin, Desmocollin, AURKAIP-1, CSNK2A2), multiplexed immunoassay and flow cytometry serum, algorithm reported as risk score;
- 0022U - Targeted genomic sequence analysis panel, non-small cell lung neoplasia, DNA and RNA analysis, 23 genes, interrogation for sequence variants and rearrangements, reported as presence/absence of variants and associated therapy(ies) to consider; and
- 0023U - Oncology (acute myelogenous leukemia), DNA, genotyping of internal tandem duplication, p.D835, p.I836, using mononuclear cells, reported as detection or non-detection of FLT3 mutation and indication for or against the use of midostaurin.

The HCPCS code, 0011M, Oncology, prostate cancer, mRNA expression assay of 12 genes (10 content and 2 housekeeping), RT-PCR test utilizing blood plasma and/or urine, algorithms to predict high-grade prostate cancer risk, was added on January 1, 2018, was not mentioned in a

previous transmittal, and is subject to CLIA edits. This HCPCS code requires 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) will not be paid for these tests.

The HCPCS codes listed below were added on April 1, 2018, and are subject to CLIA edits. 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) will not be paid for these tests.

- 0012M - Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (mdk, hoxa13, cdc2 [cdk1], igfbp5, and cxcr2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma
- 0013M - Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (mdk, hoxa13, cdc2 [cdk1], igfbp5, and cxcr2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma
- 0035U - Testing for presence of prion protein in cerebrospinal fluid
- 0036U - Exome gene analysis for somatic mutation in tumor tissue
- 0037U - DNA gene analysis of 324 genes in solid organ tumor tissue
- 0038U - Measurement of vitamin D in serum
- 0039U - Testing for anti-DNA antibody
- 0040U - BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative
- 0041U - IgM antibody detection test for Borrelia burgdorferi
- 0042U - IgG antibody detection test for Borrelia burgdorferi
- 0043U - IgM antibody detection test for Tick-Borne Relapsing Fever Borrelia group
- 0044U - IgG antibody detection test for Tick-Borne Relapsing Fever Borrelia group

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- 0045U - mRNA gene analysis of 12 genes in breast ductal carcinoma in situ tumor tissue
- 0046U - Gene analysis (fms-related tyrosine kinase 3) for internal tandem duplication variants
- 0047U - mRNA gene analysis of 17 genes in prostate tumor tissue
- 0048U - DNA gene analysis of 468 genes in solid organ tumor tissue

- 0049U - Gene analysis (nucleophosmin)
- 0050U - DNA gene analysis of targeted sequences in 194 genes for acute myelogenous leukemia
- 0051U - Testing for presence of 31 prescription drugs in urine
- 0052U - Measurement of all five major lipoprotein classes and subclasses in blood
- 0053U - FISH analysis of 4 genes in prostate needle biopsy specimen
- 0054U - Measurement of 14 or more drug classes in capillary blood
- 0055U - DNA gene analysis of 96 target sequences in plasma for heart transplant
- 0056U - Whole genome sequencing in blood or bone marrow for acute myelogenous leukemia
- 0057U - mRNA gene analysis of 51 genes in solid organ tumor tissue
- 0058U - Measurement of antibodies to Merkel cell polyoma virus oncoprotein in serum
- 0059U - Test for presence of antibodies to Merkel cell polyoma virus oncoprotein in serum
- 0060U - Gene analysis for identical twins in maternal blood

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- 0062U - Autoimmune (systemic lupus erythematosus), igg and igm analysis of 80 biomarkers, utilizing serum, algorithm reported with a risk score
- 0063U - Neurology (autism), 32 amines by lc-ms/ms, using plasma, algorithm reported as metabolic signature associated with autism spectrum disorder
- 0064U - Antibody, treponema pallidum, total and rapid plasma reagin (rpr), immunoassay, qualitative
- 0065U - Syphilis test, non-treponemal antibody, immunoassay, qualitative (rpr)
- 0066U - Placental alpha-micro globulin-1 (pamg-1), immunoassay with direct optical observation, cervico-vaginal fluid, each specimen
- 0067U - Oncology (breast), immunohistochemistry, protein expression profiling of 4 biomarkers (matrix metalloproteinase-1 [mmp-1], carcinoembryonic antigen-related cell adhesion molecule 6 [ceacam6], hyaluronoglucosaminidase [hyal1], highly expressed in cancer protein [hec1]), formalin-fixed paraffin-embedded precancerous breast tissue, algorithm reported as carcinoma risk score
- 0068U - Candida species panel (c. albicans, c. glabrata, c. parapsilosis, c. kruseii, c tropicalis, and c. auris), amplified probe technique with qualitative report of the presence or absence of each species
- 0069U - Oncology (colorectal), microrna, RT-PCR expression profiling of mir-31-3p, formalin-fixed paraffin-embedded tissue, algorithm reported as an expression sco

- 0070U - Cyp2d6 (cytochrome p450, family 2, subfamily d, polypeptide 6) (eg, drug metabolism) gene analysis, common and select rare variants (ie, *2, *3, *4, *4n, *5, *6, *7, *8, *9, *10, *11, *12, *13, *14a, *14b, *15, *17, *29, *35, *36, *41, *57, *61, *63, *68, *83, *xn)
- 0071U - Cyp2d6 (cytochrome p450, family 2, subfamily d, polypeptide 6) (eg, drug metabolism) gene analysis, full gene sequence (list separately in addition to code for primary procedure)
- 0072U - Cyp2d6 (cytochrome p450, family 2, subfamily d, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, cyp2d6-2d7 hybrid gene) (list separately in addition to code for primary procedure)
- 0073U - Cyp2d6 (cytochrome p450, family 2, subfamily d, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, cyp2d7-2d6 hybrid gene) (list separately in addition to code for primary procedure)
- 0074U - Cyp2d6 (cytochrome p450, family 2, subfamily d, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, non-duplicated gene when duplication/multiplication is trans) (list separately in addition to code for primary procedure);
- 0075U - Cyp2d6 (cytochrome p450, family 2, subfamily d, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, 5' gene duplication/multiplication) (list separately in addition to code for primary procedure)
- 0076U - Cyp2d6 (cytochrome p450, family 2, subfamily d, polypeptide 6) (eg, drug metabolism) gene analysis, targeted sequence analysis (ie, 3' gene duplication/ multiplication) (list separately in addition to code for primary procedure)
- 0077U - Immunoglobulin paraprotein (m-protein), qualitative, immunoprecipitation and mass spectrometry, blood or urine, including isotype
- 0078U - Pain management (opioid-use disorder) genotyping panel, 16 common variants (ie, abcb1, comt, dat1, dbh, dor, drd1, drd2, drd4, gaba, gal, htr2a, httlpr, mthfr, muor, oprk1, oprm1), buccal swab or other germline tissue sample, algorithm reported as positive or negative risk of opioid-use disorder

The HCPCS codes listed below are new for 2019 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) will not be paid for these tests.

- 0080U - Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy
- 0081U - Oncology (uveal melanoma), mRNA, gene-expression profiling by real-time RT-PCR of 15 genes (12 content and 3 housekeeping genes), utilizing fine needle aspirate or formalin-fixed paraffin-embedded tissue, algorithm reported as risk of metastasis

- 0082U - Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service
- 0083U - Oncology, response to chemotherapy drugs using motility contrast tomography, fresh or frozen tissue, reported as likelihood of sensitivity or resistance to drugs or drug combinations
- 81163 - BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, dna repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis)
- 81164 - BRCA1 (BRCA1, DNA repair associated), BRCA2 (BRCA2, dna repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
- 81165 - BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full sequence analysis
- 81166 - BRCA1 (BRCA1, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
- 81167 - BRCA2 (BRCA2, DNA repair associated) (eg, hereditary breast and ovarian cancer) gene analysis; full duplication/deletion analysis (ie, detection of large gene rearrangements)
- 81171 - AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile X mental retardation 2 [FRAXE]) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
- 81172 - AFF2 (AF4/FMR2 family, member 2 [FMR2]) (eg, fragile x mental retardation 2 [FRAXE]) gene analysis; characterization of alleles (eg, expanded size and methylation status)
- 81173 - AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, kennedy disease, X chromosome inactivation) gene analysis; full gene sequence
- 81174 - AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, kennedy disease, X chromosome inactivation) gene analysis; known familial variant
- 81177 - ATN1 (atrophin 1) (eg, dentatorubral-pallidoluysian atrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
- 81178 - ATXN1 (ATAXIN 1) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
- 81179 - ATXN2 (ATAXIN 2) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
- 81180 - ATXN3 (ATAXIN 3) (eg, spinocerebellar ataxia, machado-joseph disease) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
- 81181 - ATXN7 (ATAXIN 7) (EG, SPINOCEREBELLAR ATAXIA) GENE ANALYSIS, EVALUATION TO DETECT abnormal (eg, expanded) alleles
- 81182 - atxn8os (atxn8 opposite strand [non-protein coding]) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
- 81183 - ATXN10 (ATAXIN 10) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles

- 81184 - CACNA1A (calcium voltage-gated channel subunit alpha1 a) (eg, spinocerebellar ataxia) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
- 81185 - CACNA1A (calcium voltage-gated channel subunit alpha1 a) (eg, spinocerebellar ataxia) gene analysis; full gene sequence
- 81186 - CACNA1A (calcium voltage-gated channel subunit alpha1 a) (eg, spinocerebellar ataxia) gene analysis; known familial variant
- 81187 - CNBP (CCHC-type zinc finger nucleic acid binding protein) (eg, myotonic dystrophy type 2) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
- 81188 - CSTB (cystatin B) (eg, unverricht-lundborg disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
- 81189 - CSTB (cystatin B) (eg, unverricht-lundborg disease) gene analysis; full gene sequence
- 81190 - CSTB (cystatin B) (eg, unverricht-lundborg disease) gene analysis; known familial variant(s)
- 81204 - AR (androgen receptor) (eg, spinal and bulbar muscular atrophy, kennedy disease, x chromosome inactivation) gene analysis; characterization of alleles (eg, expanded size or methylation status)
- 81233 - BTK (bruton's tyrosine kinase) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, C481S, C481R, C481F)
- 81234 - DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; evaluation to detect abnormal (expanded) alleles
- 81236 - EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, myelodysplastic syndrome, myeloproliferative neoplasms) gene analysis, full gene sequence;
- 81237 - EZH2 (enhancer of zeste 2 polycomb repressive complex 2 subunit) (eg, diffuse large B-cell lymphoma) gene analysis, common variant(s) (eg, codon 646)
- 81239 - DMPK (DM1 protein kinase) (eg, myotonic dystrophy type 1) gene analysis; characterization of alleles (eg, expanded size)
- 81271 - HTT (huntingtin) (eg, huntington disease) gene analysis; evaluation to detect abnormal (eg, expanded) alleles
- 81274 - HTT (huntingtin) (eg, huntington disease) gene analysis; characterization of alleles (eg, expanded size)
- 81284 - FXN (frataxin) (eg, friedreich ataxia) gene analysis; evaluation to detect abnormal (expanded) alleles
- 81285 - FXN (frataxin) (eg, friedreich ataxia) gene analysis; characterization of alleles (eg, expanded size)
- 81286 - FXN (frataxin) (eg, friedreich ataxia) gene analysis; full gene sequence
- 81289 - FXN (frataxin) (eg, friedreich ataxia) gene analysis; known familial variant(s)
- 81305 - MYD88 (myeloid differentiation primary response 88) (eg, waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, P.LEU265PRO (L265P) variant
- 81306 - NUDT15 (nudix hydrolase 15) (eg, drug metabolism) gene analysis, common variant(s) (eg, *2, *3, *4, *5, *6)

- 81312 - PABPN1 (poly[a] binding protein nuclear 1) (eg, oculopharyngeal muscular dystrophy) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
- 81320 - PLCG2 (phospholipase c gamma 2) (eg, chronic lymphocytic leukemia) gene analysis, common variants (eg, R665W, S707F, L845F)
- 81329 - SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes smn2 (survival of motor neuron 2, centromeric) analysis, if performed
- 81333 - TGFBI (transforming growth factor beta-induced) (eg, corneal dystrophy) gene analysis, common variants (eg, R124H, R124C, R124L, R555W, R555Q)
- 81336 - SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; full gene sequence
- 81337 - smn1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; known familial sequence variant(s)
- 81343 - PPP2R2B (protein phosphatase 2 regulatory subunit Bbeta) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
- 81344 - TBP (TATA box binding protein) (eg, spinocerebellar ataxia) gene analysis, evaluation to detect abnormal (eg, expanded) alleles
- 81345 - TERT (telomerase reverse transcriptase) (eg, thyroid carcinoma, glioblastoma multiforme) gene analysis, targeted sequence analysis (eg, promoter region)
- 81443 - genetic testing for severe inherited conditions (eg, cystic fibrosis, ashkenazi jewish-associated disorders [eg, bloom syndrome, canavan disease, fanconi anemia type C, mucolipidosis type vi, gaucher disease, tay-sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (eg, ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH)
- 81518 - Oncology (breast), mRNA, gene expression profiling by real-time RT-PCR OF 11 genes (7 content and 4 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithms reported as percentage risk for metastatic recurrence and likelihood of benefit from extended endocrine therapy
- 81596 - Infectious disease, chronic hepatitis C virus (HCV) infection, six biochemical assays; (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver
- 82642 - Dihydrotestosterone (DHT)
- 83722 - Lipoprotein, direct measurement; small dense LDL cholesterol

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.

Remember that MACs will 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).

Note: MACs will not search their files to either retract payment for claims already paid or to retroactively pay claims. However, MACs will adjust claims that you bring to their attention.

ADDITIONAL INFORMATION

The official instruction, CR11135, issued to your MAC regarding this change is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2019Downloads/R4245CP.pdf.

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

Date of Change	Description
February 22, 2019	Initial article released.