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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: MM12573
Related Change Request (CR) Number: 12573
Related CR Release Date: January 20, 2022
Effective Date: April 1, 2022
Related CR Transmittal Number: R11208CP
Implementation Date: April 4, 2022

Provider Types Affected

This MLN Matters Article is for laboratories, physicians, and hospitals billing Medicare Administrative Contractors (MACs) for laboratory services they provide to Medicare patients.

Provider Action Needed

In this Article, you'll learn about:

- Discontinued HCPCS codes
- New HCPCS codes
- Which HCPCS codes are subject to and excluded from Clinical Laboratory Improvement Amendments (CLIA) edits

Make sure your billing staff knows about these changes.

Background

The CLIA regulations require a facility to be properly certified for each test it performs. To make sure Medicare and Medicaid only pay for laboratory tests performed in certified facilities, each claim for a HCPCS code considered a CLIA laboratory test is edited at the CLIA certificate level. The HCPCS codes considered a laboratory test under CLIA change each year.

The following HCPCS codes were discontinued on March 31, 2021:

- 0098U - Test for detection of respiratory disease-causing organism using amplified probe, 14 target organisms
- 0099U - Test for detection of respiratory disease-causing organism using amplified probe, 20 target organisms (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus, coronavirus OC43, human metapneumovirus, influenza A, influenza A subtype, influenza A subtype H3, influenza A subtype H1-2009, influenza, parainfluenza

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virus, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, human rhinovirus/enterovirus, respiratory syncytial virus, Bordetella pertussis, Chlamydophila pneumonia, Mycoplasma pneumoniae)
- 0100U - Test for detection of respiratory disease-causing organism using amplified probe, 21 target organisms (adenovirus, coronavirus 229E, coronavirus HKU1, coronavirus NL63, coronavirus OC43, human metapneumovirus, human rhinovirus/enterovirus, influenza A, including subtypes H1, H1-2009, and H3, influenza B, parainfluenza virus 1, parainfluenza virus 2, parainfluenza virus 3, parainfluenza virus 4, respiratory syncytial virus, Bordetella parapertussis [IS1001], Bordetella pertussis [ptxP], Chlamydia pneumoniae, Mycoplasma pneumoniae)

The following HCPCS codes were discontinued on September 30, 2021:

- 0139U - Measurement of 6 central carbon metabolite biomarkers for autism spectrum disorder in plasma
- 0168U - DNA analysis for detection of abnormal chromosome number of the fetus in maternal plasma specimen

The following HCPCS codes were discontinued on December 31, 2021:

- 0208U - mRNA gene analysis of 108 genes in fine needle aspiration thyroid specimen, reported as positive or negative for medullary thyroid carcinoma
- 80500 - Clinical pathology consultation
- 80502 - Comprehensive, clinical pathology consultation

The following HCPCS codes are excluded from CLIA edits (effective as noted) and don't need the facility to have any CLIA certificate:

- 0254U - reimplantation genetic assessment of embryo by gene sequence analysis of 24 chromosomes for abnormal chromosome number - Effective July 1, 2021
- 0294U - Longevity and mortality risk, mrna, gene expression profiling by rna sequencing of 18 genes, whole blood, algorithm reported as predictive risk score - Effective January 1, 2022
- 80503 - Pathology clinical consultation for clinical problem, 5-20 minutes - Effective January 1, 2022
- 80504 - Pathology clinical consultation for moderately complex clinical problem, 21-40 minutes - Effective January 1, 2022
- 80505 - Pathology clinical consultation for complex clinical problem, 41-60 minutes - Effective January 1, 2022
- 80506 - Pathology clinical consultation, additional 30 minutes - Effective January 1, 2022

The HCPCS codes that follow are all subject to CLIA edits. These lists don't include new HCPCS codes for waived tests or provider-performed microscopy procedures. All these HCPCS codes 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 paid for these tests, unless a facility with a current CLIA certificate of waiver (certificate type code 2) or CLIA certificate for provider-performed microscopy procedures (certificate type code 4) bills the proper HCPCS service code with a QW modifier.

We added the following HCPCS codes on April 1, 2021, and they're subject to CLIA edits:

- 0242U - Gene analysis of 55-74 genes associated with solid organ cancer in cell-free circulating DNA, targeted genomic sequence
- 0243U - Time-resolved fluorescence immunoassay of placental-growth factor in maternal serum to evaluate risk of preeclampsia
- 0244U - Gene analysis of 257 genes associated with solid organ cancer in tumor tissue sample, comprehensive genomic profiling
- 0245U - Gene analysis of 10 genes and 37 RNA fusions and expression of 4 mRNA markers, next-generation sequencing, in fine needle aspirate of thyroid to evaluate risk of thyroid cancer
- 0246U - Blood typing for 16 or more blood groups with phenotype prediction of 51 or more red blood cell antigens
- 0247U - Quantitative measurement of insulin-like growth factor-binding protein 4 and sex hormone-binding globulin (SHBG) in maternal serum by LC-MS/MS to evaluate risk of premature birth

We added the following HCPCS codes on July 1, 2021, and they're subject to CLIA edits:

- 0248U - Culture of brain cancer cells with 12 drug panel testing for tumor response prediction
- 0249U - Analysis of 32 phosphoproteins and protein analytes associated with breast cancer, with interpretation and report
- 0250U - Gene analysis of 505 genes associated with solid organ cancer in tumor tissue sample, targeted genomic sequence interrogation for somatic alterations, microsatellite instability and tumor-mutation burden
- 0251U - ELISA assay for hepcidin-25 in serum or plasma
- 0252U - Analysis of fetal DNA, short tandem-repeat comparative analysis, for abnormal chromosome number
- 0253U - RNA gene expression profiling of 238 genes by next-generation sequencing specimen from lining of womb to evaluate window of implantation for embryo transfer
- G0327 - Colorectal cancer screening; blood-based biomarker

We added the following HCPCS codes on October 1, 2021, and they're subject to CLIA edits:

- 0018M - Measurement of kidney donor and third-party-induced CD154+T-cytotoxic memory cells in whole peripheral blood specimen, algorithm reported as kidney transplant rejection risk score

- 0255U - Evaluation of sperm using fluorescence microscopic evaluation of ganglioside GM1 distribution patterns, reported as percentage of capacitated sperm and probability of generating pregnancy score
- 0256U - Tandem mass spectroscopy (MS/MS) profile of trimethylamine/trimethylamine N-oxide (TMA/TMAO) profile in urine, with algorithmic analysis and interpretive report
- 0257U - Evaluation of very long chain acyl-coenzyme A (CoA) dehydrogenase (VLCAD) white blood cell enzyme activity in whole blood
- 0258U - mRNA gene expression profiling of 50-100 genes in skin surface specimen, algorithm reported as likelihood of response to psoriasis biologics
- 0259U - Nuclear MR spectroscopy measurement of myo-inositol, valine, and creatinine, algorithmically combined with cystatin C (by immunoassay) and demographic data to evaluate kidney function
- 0260U - Optical genome mapping for detection of abnormalities associated with rare heritable diseases
- 0261U - Image analysis with artificial intelligence assessment of 4 cellular and immune features in colorectal cancer tumor tissue specimen, reported as immune response and recurrence-risk score
- 0262U - mRNA gene expression profiling of 7 gene pathways in solid organ tumor tissue specimen, algorithm reported as gene pathway activity score
- 0263U - LC-MS/MS spectroscopy of 16 central carbon metabolites associated with autism spectrum disorders (ASD) in plasma specimen, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)
- 0264U - Detection of abnormalities associated with rare heritable diseases by optical genome mapping
- 0265U - Whole genome and mDNA sequence analysis for detection of abnormalities associated with rare constitutional/heritable diseases
- 0266U - Gene expression profiling by whole transcriptome and next-generation sequencing for detection of unexplained heritable disease
- 0267U - Optical genome mapping and whole genome sequencing for detection of abnormalities associated with rare heritable diseases
- 0268U - Genomic sequence analysis of 15 genes for detection of abnormalities associated with atypical hemolytic uremic syndrome
- 0269U - Genomic sequence analysis of 14 genes for detection of abnormalities associated with autosomal dominant congenital thrombocytopenia (low platelet count)
- 0270U - Genomic sequence analysis of 20 genes for detection of abnormalities associated with congenital coagulation disorders (blood clotting disorders)
- 0271U - Genomic sequence analysis of 23 genes for detection of abnormalities associated with congenital neutropenia (low white blood cell count)
- 0272U - Comprehensive genomic sequence analysis of 51 genes for detection of abnormalities associated with congenital bleeding disorders
- 0273U - Genomic sequence analysis of 8 genes for detection of abnormalities associated with genetic hyperfibrinolysis and delayed bleeding
- 0274U - Genomic sequence analysis of 43 genes for detection of abnormalities associated with genetic platelet disorders

- 0275U - Flow cytometry detection of platelet antibody reactivity in serum for evaluation of heparin-induced thrombocytopenia (low platelet count due to heparin)
- 0276U - Genomic sequence analysis of 23 genes for detection of abnormalities associated with inherited thrombocytopenia (low platelet count)
- 0277U - Genomic sequence analysis of 31 genes for detection of abnormalities associated with genetic platelet function disorder
- 0278U - Genomic sequence analysis of 12 genes for detection of abnormalities associated with genetic thrombosis (excessive clotting)
- 0279U - ELISA detection of von Willebrand factor (VWF) and collagen III binding in plasma specimen, report of collagen III binding
- 0280U - ELISA detection of von Willebrand factor (VWF) and collagen IV binding in plasma specimen, report of collagen IV binding
- 0281U - ELISA measurement of von Willebrand propeptide in plasma specimen, diagnostic report of von Willebrand factor (VWF) propeptide antigen level
- 0282U - Red blood cell antigen genotyping of 12 blood group system genes to predict 44 red blood cell antigen phenotypes
- 0283U - Radioimmunoassay platelet-binding evaluation of von Willebrand factor (VWF), type 2B, in plasma specimen
- 0284U - ELISA evaluation of von Willebrand factor (VWF), type 2N, factor VIII and VWF binding in plasma specimen

We added the following HCPCS codes on January 1, 2022, and they're subject to CLIA edits:

- 0285U - Oncology, response to radiation, cell-free dna, quantitative branched chain dna amplification, plasma, reported as a radiation toxicity score
- 0286U - Cep72 (centrosomal protein, 72-kda), nudt15 (nudix hydrolase 15) and tpmt (thiopurine s-methyltransferase) (eg, drug metabolism) gene analysis, common variants
- 0287U - Oncology (thyroid), dna and mrna, next-generation sequencing analysis of 112 genes, fine needle aspirate or formalin-fixed paraffin-embedded (ffpe) tissue, algorithmic prediction of cancer recurrence, reported as a categorical risk result (low, intermediate, high)
- 0288U - Oncology (lung), mrna, quantitative pcr analysis of 11 genes (bag1, brca1, cdc6, cdk2ap1, erbb3, fut3, il11, lck, rnd3, sh3bgr, wnt3a) and 3 reference genes (esd, tbp, yap1), formalin-fixed paraffin-embedded (ffpe) tumor tissue, algorithmic interpretation reported as a recurrence risk score
- 0289U - Neurology (alzheimer disease), mrna, gene expression profiling by rna sequencing of 24 genes, whole blood, algorithm reported as predictive risk score;
- 0290U - Pain management, mrna, gene expression profiling by rna sequencing of 36 genes, whole blood, algorithm reported as predictive risk score
- 0291U - Psychiatry (mood disorders), mrna, gene expression profiling by rna sequencing 144 genes, whole blood, algorithm reported as predictive risk score
- 0292U - Psychiatry (stress disorders), mrna, gene expression profiling by rna sequencing of 72 genes, whole blood, algorithm reported as predictive risk score
- 0293U - Psychiatry (suicidal ideation), mrna, gene expression profiling by rna sequencing of 54 genes, whole blood, algorithm reported as predictive risk score

- 0295U - Oncology (breast ductal carcinoma in situ), protein expression profiling by immunohistochemistry of 7 proteins (cox2, foxa1, her2, ki-67, p16, pr, siah2), with 4 clinicopathologic factors (size, age, margin status, palpability), utilizing formalin-fixed paraffin-embedded (ffpe) tissue, algorithm reported as a recurrence risk score
- 0296U - Oncology (oral and/or oropharyngeal cancer), gene expression profiling by rna sequencing at least 20 molecular features (eg, human and/or microbial mrna), saliva, algorithm reported as positive or negative for signature associated with malignancy
- 0297U - Oncology (pan tumor), whole genome sequencing of paired malignant and normal dna specimens, fresh or formalin-fixed paraffin-embedded (ffpe) tissue, blood or bone marrow, comparative sequence analyses and variant identification
- 0298U - Oncology (pan tumor), whole transcriptome sequencing of paired malignant and normal rna specimens, fresh or formalin-fixed paraffin-embedded (ffpe) tissue, blood or bone marrow, comparative sequence analyses and expression level and chimeric transcript identification0299U - Oncology (pan tumor), whole genome optical genome mapping of paired malignant and normal dna specimens, fresh frozen tissue, blood, or bone marrow, comparative structural variant identification
- 0300U - Oncology (pan tumor), whole genome sequencing and optical genome mapping of paired malignant and normal dna specimens, fresh tissue, blood, or bone marrow, comparative sequence analyses and variant identification
- 0301U - Infectious agent detection by nucleic acid (dna or rna), bartonella henselae and bartonella quintana, droplet digital pcr (ddpcr)
- 0302U - Infectious agent detection by nucleic acid (dna or rna), bartonella henselae and bartonella quintana, droplet digital pcr (ddpcr); following liquid enrichment
- 0303U - Hematology, red blood cell (rbc) adhesion to endothelial/subendothelial adhesion molecules, functional assessment, whole blood, with algorithmic analysis and result reported as an rbc adhesion index; hypoxic
- 0304U - Hematology, red blood cell (rbc) adhesion to endothelial/subendothelial adhesion molecules, functional assessment, whole blood, with algorithmic analysis and result reported as an rbc adhesion index; normoxic
- 0305U - Hematology, red blood cell (rbc) functionality and deformity as a function of shear stress, whole blood, reported as a maximum elongation index
- 80220 - Measurement of hydroxychloroquine
- 81349 - Genome-wide microarray analysis for copy number and loss-of-heterozygosity variants
- 81523 - Next-generation sequencing of breast cancer profiling 70 content genes and 31 housekeeping genes
- 81560 - Measurement of donor and third-party memory cells for transplantation medicine
- 82653 - Measurement of pancreatic elastase (enzyme) in stool
- 83521 - Measurement of immunoglobulin light chains
- 83529 - Measurement of interleukin-6
- 86015 - Measurement of Actin (smooth muscle) antibody
- 86036 - Screening test for antineutrophil cytoplasmic antibody
- 86037 - Antineutrophil cytoplasmic antibody titer
- 86051 - ELISA detection of aquaporin-4 (neuromyelitis optica [NMO]) antibody

- 86052 - Cell-based immunofluorescence (CBA) detection of aquaporin-4 (neuromyelitis optica [NMO]) antibody
- 86053 - Flow cytometry detection of aquaporin-4 (neuromyelitis optica [NMO]) antibody;
- 86231 - Detection of endomysial antibody (EMA)
- 86258 - Detection of gliadin (deamidated) (DGP) antibody
- 86362 - Cell-based immunofluorescence (CBA) detection of myelin oligodendrocyte glycoprotein (MOG-IgG1) antibody
- 86363 - Flow cytometry detection of myelin oligodendrocyte glycoprotein (MOG-IgG1) antibody
- 86364 - Measurement of tissue transglutaminase
- 86381 - Measurement of mitochondrial antibody
- 86596 - Measurement of voltage-gated calcium channel antibody
- 87154 - Amplified nucleic acid probe typing of disease agent in blood culture specimen.

NOTE: This instruction is NOT intended to rescind or replace any previous instructions showing that a laboratory with a valid CLIA certificate of waiver or CLIA certificate for provider-performed microscopy procedures be allowed to bill the above codes with a QW modifier.

MACs won't search their files to either retract payment for claims already paid or to retroactively pay claims. However, they'll adjust such claims you bring to their attention.

More Information

We issued CR 12573 to your MAC as the official instruction for this change.

For more information, find your MAC's website.

Document History

Date of Change	Description
January 20, 2022	Initial article released.

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