



## HCPCS Codes & Clinical Laboratory Improvement Amendments Edits: April 2023

MLN Matters Number: MM13024

Related Change Request (CR) Number: 13024

Related CR Release Date: December 8, 2022

Effective Date: April 1, 2023

Related CR Transmittal Number: R11735CP

Implementation Date: April 3, 2023

Related CR Title: 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 for physicians, other providers, and suppliers billing Medicare Administrative Contractors (MACs) for services they provide to Medicare patients.

### Provider Action Needed

---

Make sure your billing staff knows about these changes:

- New HCPCS codes
- Discontinued HCPCS codes
- Required CLIA certificates

### Background

---

The CLIA regulations require a facility to be appropriately certified for each test performed. To make sure that Medicare & Medicaid only pay for laboratory tests performed in certified facilities, CMS edits each claim for a HCPCS code that's considered a CLIA laboratory test at the CLIA certificate level.

The following HCPCS codes were discontinued on March 31, 2022:

- 0097U - Test for detection of gastrointestinal disease-causing organism using amplified probe
- 0151U - Test for detection of respiratory disease-causing organisms in sputum or respiratory tract specimen, 33 target organismal and antibiotic resistance.

The following HCPCS codes were discontinued on September 30, 2022:

- 0012U - Gene analysis for germline disorder
- 0013U - Gene analysis of solid organ tumor tissue
- 0014U - DNA test for detecting gene abnormality associated with blood and lymphatic system cancer in blood or bone marrow
- 0056U - Whole genome sequencing in blood or bone marrow for acute myelogenous leukemia

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. These HCPCS codes all require a facility to have either a:

- CLIA certificate of registration (certificate type code 9)
- CLIA certificate of compliance (certificate type code 1)
- 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) isn't paid for these tests, unless a facility with a current certificate type code 2 or 4) bills the appropriate HCPCS service code with a QW modifier.

The HCPCS code listed below was added on February 21, 2022, and is subject to CLIA edits:

- 87913 - Genotype analysis of severe acute respiratory syndrome coronavirus 2 (COVID-19) by nucleic acid for identification of mutations in targeted regions

The HCPCS codes listed below were added on April 1, 2022, and are subject to CLIA edits.

- 0306U - Initial baseline gene analysis for minimum residual disease in cancer, next-generation targeted sequencing analysis of cell-free DNA, to determine a patient specific panel for future comparisons
- 0307U - Subsequent gene analysis for minimum residual disease in cancer, next-generation targeted sequencing analysis of cell-free DNA, to determine a patient specific panel for future comparisons
- 0308U - Analysis of 3 proteins (high sensitivity [hs] troponin, adiponectin, and kidney injury molecule-1 [KIM-1]) in plasma specimen, algorithm reported as risk score for obstructive coronary artery disease
- 0309U - Analysis of 4 proteins (NT-proBNP, osteopontin, tissue inhibitor of metalloproteinase-1 [TIMP-1], and kidney injury molecule-1 [KIM-1]) in plasma specimen, algorithm reported as risk score for major adverse heart event
- 0310U - Analysis of 3 biomarkers (NT-proBNP, C-reactive protein, and T-uptake) for Kawasaki disease (KD) in plasma specimen, algorithm reported as risk score for KD
- 0311U - Measurement of bacterial susceptibility to antibiotics, reported as phenotypic minimum inhibitory concentration (MIC) for each organism identified
- 0312U - Analysis of 8 IgG autoantibodies and 2 cell-bound complement activation products associated with autoimmune disease, using enzyme-linked immunosorbent

immunoassay (ELISA), flow cytometry and indirect immunofluorescence in serum specimen or plasma and whole blood specimen, individual components reported along with algorithmic systemic lupus erythematosus-likelihood assessment

- 0313U - DNA and mRNA next-generation sequencing analysis of 74 genes and analysis of CEA (CEACAM5) gene expression in pancreatic cyst fluid specimen, algorithm reported as negative, low probability of cancer of pancreas or positive, high probability of cancer of pancreas
- 0314U - mRNA gene expression profiling by real-time polymerase chain reaction (RT-PCR) of 35 genes (32 content and 3 housekeeping) associated with melanoma of skin in formalin-fixed paraffin-embedded (FFPE) tissue specimen, algorithm reported as benign, intermediate, or malignant
- 0315U - mRNA gene expression profiling by real-time polymerase chain reaction (RT-PCR) of 40 genes (34 content and 6 housekeeping) associated with squamous cell carcinoma of skin in formalin-fixed paraffin-embedded (FFPE) tissue specimen, algorithm reported as benign, intermediate, or malignant
- 0316U - Evaluation of outer surface protein A (OspA) of *Borrelia burgdorferi* (Lyme disease) in urine specimen
- 0317U - Four-probe fluorescence in situ hybridization (FISH) (3q29, 3p22.1, 10q22.3, 10cen) assay of whole blood specimen, predictive algorithm-generated evaluation reported as decreased or increased risk for lung cancer
- 0318U - Whole genome methylation analysis by microarray for 50 or more genes associated with congenital epigenetic disorders in blood specimen
- 0319U - RNA gene expression profiling by select transcriptome sequencing in peripheral blood specimen taken before kidney transplant, algorithm reported as risk score for early acute rejection
- 0320U - RNA gene expression profiling by select transcriptome sequencing in peripheral blood specimen taken after kidney transplant, algorithm reported as risk score for acute cellular rejection
- 0321U - Detection test by nucleic acid (DNA or RNA) multiplex amplified probe technique for identification of 20 bacterial and fungal organisms associated with genital or urinary tract infection and identification of 16 associated antibiotic-resistance genes
- 0322U - Measurement of 14 acyl carnitines and microbiome-derived metabolites associated with autism spectrum disorders by liquid chromatography with tandem mass spectrometry (LC-MS/MS) in plasma specimen, results reported as negative or positive for risk of metabolic subtypes associated with autism spectrum disorders

The HCPCS codes listed below were added on July 1, 2022, and are subject to CLIA edits.

- 0323U - DNA and mRNA next-generation sequencing analysis in cerebrospinal fluid specimen for detection of organisms causing disease in central nervous system
- 0324U - Culture of spheroid ovarian cancer cells for evaluation of 4 drugs (carboplatin, doxorubicin, gemcitabine, paclitaxel), result reported as tumor chemotherapy response prediction for each drug
- 0325U - Culture of spheroid ovarian cancer cells for evaluation of poly (ADP-ribose) polymerase (PARP) inhibitors (niraparib, olaparib, rucaparib, velparib), result reported as tumor chemotherapy response prediction for each drug

- 0326U - Targeted genomic sequence analysis of 83 or more genes in cell free circulating DNA for detection of abnormalities associated with solid organ cancers
- 0327U - DNA sequence analysis of selected regions for detection of abnormal fetal chromosome number (trisomy 13, 18, and 21) in maternal plasma specimen, algorithm reported as risk score for each trisomy, includes sex reporting, if performed
- 0328U - Definitive drug testing for 120 or more drugs and metabolites in urine specimen
- 0329U - Exome and transcriptome sequence analysis of DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutations with therapy associations
- 0330U - Amplified nucleic acid probe for identification of 27 vaginal disease agents in vaginal swab specimen
- 0331U - Optical genome mapping of DNA from blood or bone marrow specimen, report of clinically significant alterations associated with blood or lymph system cancers

The HCPCS code listed below was added on July 26, 2022, and is subject to CLIA edits.

- 87593 - Infectious agent detection by nucleic acid (dna or rna); orthopoxvirus (e.g., monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each

The HCPCS codes listed below were added on October 1, 2022, and are subject to CLIA edits.

- 0332U - Genetic profiling of 8 epigenetic markers to evaluate probability of responding to immune checkpoint-inhibitor therapy for cancer
- 0333U - Surveillance for liver cancer in high risk patients using algorithm
- 0334U - Targeted genomic sequence analysis of 84 or more genes for detection of abnormalities associated with cancer of body organ
- 0335U - Whole genome sequence analysis of fetal sample for detection of abnormalities associated with rare constitutional/heritable diseases
- 0336U - Whole genome sequence analysis of comparator genome (parent) for detection of abnormalities associated with rare constitutional/heritable diseases
- 0337U - Evaluation of plasma cells for detection of abnormalities associated with plasma cell disorders and myeloma
- 0338U - Evaluation of circulating solid tumor cells in peripheral blood
- 0339U - mRNA expression profiling of genes associated with high-grade prostate cancer
- 0340U - DNA assays for detection of minimal residual disease in cancer
- 0341U - Fetal DNA sequencing of products of conception for detection of abnormal chromosome number
- 0342U - Multiplex immunoassay for markers of pancreatic cancer in serum
- 0343U - Exosome-based analysis of 442 small noncoding RNAs in urine to evaluate risk of prostate cancer
- 0344U - Evaluation of 28 lipid markers for risk of nonalcoholic fatty liver disease
- 0345U - Genomic analysis panel of 15 genes for detection of abnormalities associated with mental health disorders
- 0346U - Evaluation of Beta amyloid AB40 and AB42 ratio
- 0347U - DNA analysis of 16 genes involved in drug metabolism or processing

- 0348U - DNA analysis of 25 genes involved in drug metabolism or processing
- 0349U - DNA analysis of 27 genes involved in drug metabolism or processing, report including gene-drug interactions
- 0350U - DNA analysis of 27 genes involved in drug metabolism or processing, analysis and reported phenotypes
- 0351U - Biochemical assays for markers of bacterial infecti
- 0352U - Detection of bacteria causing vaginosis and vaginitis by multiplex amplified nucleic acid probe technique
- 0353U - Detection of Chlamydia trachomatis and Neisseria gonorrhoeae by multiplex amplified DNA probe technique
- 0354U - Human papilloma virus (HPV) by quantitative polymerase chain reaction (qPCR)

The HCPCS codes listed below are added on January 1, 2023, and are subject to CLIA edits.

- 0355U – Apol1 (apolipoprotein I1) (eg, chronic kidney disease), risk variants (g1, g2)
- 0356U – Oncology (oropharyngeal), evaluation of 17 dna biomarkers using droplet digital pcr (ddpcr), cell-free dna, algorithm reported as a prognostic risk score for cancer recurrence
- 0357U – Oncology (melanoma), artificial intelligence (ai)-enabled quantitative mass spectrometry analysis of 142 unique pairs of glycopeptide and product fragments, plasma, prognostic, and predictive algorithm reported as likely, unlikely, or uncertain benefit from immunotherapy agents
- 0358U - Neurology (mild cognitive impairment), analysis of b-amyloid 1-42 and 1-40, chemiluminescence enzyme immunoassay, cerebral spinal fluid, reported as positive, likely positive, or negative
- 0359U - Oncology (prostate cancer), analysis of all prostate-specific antigen (psa) structural isoforms by phase separation and immunoassay, plasma, algorithm reports risk of cancer
- 0360U - Oncology (lung), enzyme-linked immunosorbent assay (elisa) of 7 autoantibodies (p53, ny-eso-1, cage, gbu4-5, sox2, mage a4, and hud), plasma, algorithm reported as a categorical result for risk of malignancy
- 0361U - Neurofilament light chain, digital immunoassay, plasma, quantitative
- 0362U - Oncology (papillary thyroid cancer), gene-expression profiling via targeted hybrid capture-enrichment rna sequencing of 82 content genes and 10 housekeeping genes, formalin-fixed paraffin embedded (ffpe) tissue, algorithm reported as one of three molecular subtypes
- 0363U - Oncology (urothelial), mrna, gene expression profiling by real-time quantitative pcr of 5 genes (mdk, hoxa13, cdc2 [cdk1], igfbp5, and cxcr2), utilizing urine, algorithm incorporates age, sex, smoking history, and macrohematuria frequency, reported as a risk score for having urothelial carcinoma
- 81418 - Genomic sequence analysis panel of at least 6 genes associated with drug metabolism
- 81441 - Gene sequence analysis panel at least 30 genes associated with inherited bone marrow failure syndromes
- 81449 - Targeted genomic sequence analysis panel of RNA of 5-50 genes associated

- with solid organ neoplasm
- 81451 - Targeted genomic sequence analysis panel of RNA of 5-50 genes associated with blood and lymphatic system disorders
  - 81456 - Targeted genomic sequence analysis panel of RNA of 51 or greater genes associated with blood and lymphatic system disorders
  - 84433 - Evaluation of thiopurine S-methyltransferase (TPMT)
  - 87467 - Measurement of Hepatitis B surface antigen (HBsAg)
  - 87468 - Detection of Anaplasma phagocytophilum by amplified nucleic acid probe technique
  - 87469 - Detection of Babesia microtim by amplified nucleic acid probe technique
  - 87478 - Detection of Borrelia miyamotoi by amplified nucleic acid probe technique
  - 87484 - Detection of Ehrlichia chaffeensis by amplified nucleic acid probe technique

[CR 13024](#) doesn't rescind or replace any previous instructions indicating 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 the 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 claims you bring to their attention.

## More Information

We issued CR 13024 to your MAC as the official instruction for this change.

For more information, [find your MAC's website](#).

## Document History

Date of Change	Description
December 9, 2022	Initial article released.

[Medicare Learning Network® Content & Product Disclaimer, and Department of Health & Human Services Disclosure](#)

The Medicare Learning Network®, MLN Connects®, and MLN Matters® are registered trademarks of the U.S. Department of Health & Human Services (HHS).