CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 10009	**Date: March 20, 2020**
	Change Request 11640

Transmittal 4542, dated March 6, 2020, is being rescinded and replaced by Transmittal 10009, dated, March 20, 2020 to revise the background section removing the first instance of code 0091U. All other information remains the same.

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 (CR) informs contractors about the new HCPCS codes for 2020 that are subject to and excluded from CLIA edits. This Recurring Update Notification applies to Chapter 16, section 70.9.

EFFECTIVE DATE: April 1, 2020
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 6, 2020

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	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: 10009	Date: March 20, 2020	Change Request: 11640

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

EFFECTIVE DATE: April 1, 2020
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IMPLEMENTATION DATE: April 6, 2020

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 code was discontinued on June 30, 2019:

- 0057U - mRNA gene analysis of 51 genes in solid organ tumor tissue.

The following HCPCS code was discontinued on September 30, 2019:

- 0104U - Hereditary pan cancer (eg, hereditary breast and ovarian cancer, hereditary endometrial cancer, hereditary colorectal cancer), genomic sequence analysis panel utilizing a combination of ngs, sanger, mlpa, and array cgh, with mrna analytics to resolve variants of unknown significance when indicated (32 genes [sequencing and deletion/duplication], epcam and grem1 [deletion/duplication only]).

The following HCPCS codes were discontinued on December 31, 2019:

- 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; and
- 0085U - Evaluation of biomarker antibodies for inflammatory bowel disease.

The following HCPCS codes are new for 2020, are excluded from CLIA edits, and do not require a facility to have any CLIA certificate:

- 0106U - Evaluation of gastric emptying by measurement of radiolabeled carbon monoxide in breath specimens,

- 0126U - Analysis of 5 substances in maternal blood to assess risk of preeclampsia,

- 0128U - Analysis of 3 substances in maternal blood and analysis of Y chromosome in fetal DNA to assess risk of abnormal chromosomes in fetus and preeclampsia, and

- 0156U - Copy number (eg, intellectual disability, dysmorphology), sequence analysis.

The HCPCS codes listed below were added on July 1, 2019 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.

- 0087U – mRNA gene expression profiling of genes in heart transplant biopsy tissue to evaluate risk of rejection;

- 0088U – mRNA gene expression profiling of genes in kidney transplant tissue to evaluate risk of rejection;

- 0089 U – Gene expression profiling of melanoma in superficial sample collected by adhesive patch:

- 0090U – mRNA gene expression profiling of 23 genes in skin melanoma tissue sample;

- 0092U – Measurement of 3 protein biomarkers for lung cancer in plasma;

- 0093U – Prescription drug monitoring for 65 common drugs in urine;

- 0094U – Rapid sequence gene testing;

- 0095U – Test for markers of eosinophilic inflammation of esophagus;

- 0096U – Test for detection of high-risk human papillomavirus in male urine;

- 0097U – Test for detection of gastrointestinal disease-causing organism using amplified probe;

- 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 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, 20 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)

- 0101U – Gene sequence analysis panel of 15 genes associated with hereditary colon cancer and related disorders;

- 0102U – Gene sequence analysis panel of 17 genes associated with hereditary breast cancer and related disorders; and

- 0103U – Gene sequence analysis panel of 24 genes associated with hereditary ovarian cancer and related disorders.

The HCPCS codes listed below were added on October 1, 2019 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.

- 0105U – Measurement of tumor necrosis factor receptor 1A, receptor superfamily 2 (TNFR1, TNFR2), and kidney injury molecule-1 (KIM-1) in plasma to evaluate risk of rapid kidney function decline;

- 0107U – Antigen test for detection of Clostridium difficile toxin in stool;

- 0108U – Computer-assisted digital imaging of esophagus specimen slides to evaluate risk of cancer;

- 0109U – DNA test for detection of 4 Aspergillus species;

- 0110U – Monitoring of anti-cancer drugs in patient blood, serum, or plasma;

- 0111U - Gene analysis (KRAS and NRAS) in prostate tumor tissue;

- 0112U – Gene analysis for detection of infectious agent and drug resistance gene;
- 0113U – Measurement of PCA3 gene in urine and prostate-specific antigen (PSA) in serum to evaluate risk of prostate cancer;
- 0114U – Gene analysis (VIM and CCNA1 methylation) in esophageal cells to evaluate likelihood of precancerous changes;
- 0115U – Respiratory infectious agent detection by nucleic acid (DNA and RNA), 18 viral types and subtypes and 2;
- 0116U – Analysis of 35 or more drugs in mouth fluid to evaluate risk of prescription drug interactions;
- 0117U – Analysis of 11 biochemical substances in urine to evaluate likelihood of atypical biochemical function associated with pain;
- 0118U – Measurement of transplant donor cell-free DNA in transplant recipient plasma;
- 0119U – Measurement of ceramides for assessment of heart disease risk;
- 0120U – mRNA, gene expression profiling of 58 genes in tissue sample for B-cell lymphoma classification;
- 0121U – Blood test for sickle cells using VCAM-1;
- 0122U – Blood test for sickle cells using P-Selectin;
- 0123U – Test for fragility of red blood cells;
- 0124U – Analysis of 3 substances in maternal blood to assess risk of abnormal chromosomes in fetus;
- 0125U – Analysis of 5 substances in maternal blood to assess risk of abnormal chromosomes in fetus and preeclampsia;
- 0127U – Analysis of 3 substances in maternal blood to assess risk of preeclampsia;
- 0129U – Gene analysis of genes associated with hereditary breast cancer and related disorders for gene sequence and duplication or deletion variants;

- 0130U – Targeted mRNA sequence analysis of genes associated with hereditary colon cancer and related disorders;

- 0131U – Targeted mRNA sequence analysis of 13 genes associated with hereditary breast cancer and related disorders;

- 0132U – Targeted mRNA sequence analysis of 17 genes associated with hereditary ovarian cancer and related disorders;

- 0133U – Targeted mRNA sequence analysis of 11 genes associated with hereditary prostate cancer and related disorders;

- 0134U – Targeted mRNA sequence analysis of 18 genes associated with hereditary pan cancer;

- 0135U – Targeted mRNA sequence analysis of 12 genes associated with hereditary gynecological cancer;

- 0136U – mRNA gene analysis (ataxia telangiectasia mutated);

- 0137U – mRNA gene analysis (partner and localizer of BRCA2); and

- 0138U – mRNA gene analysis (BRCA1, DNA repair associated and BRCA2, DNA repair associated).

The HCPCS codes listed below are new for 2020 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.

- 0139U – Neurology (autism spectrum disorder [asd]), quantitative measurements of 6 central carbon metabolites (ie,ketoglutarate, alanine, lactate, phenylalanine, pyruvate, and succinate), lc-ms/ms, plasma, algorithmic analysis with result reported as negative or positive abolic subtypes of asd);

- 0140U – Infectious disease (fungi), fungal pathogen identification, dna (15 fungal targets), blood culture, amplified probe technique, each target reported as detected or not detected;

- 0141U – Infectious disease (bacteria and fungi), gram-positive organism identification and drug resistance element detection, dna (20 gram-positive bacterial targets, 4 resistance genes, 1 pan gram-

negative bacterial target, 1 pan candida target), blood culture, amplified probe technique, each target reported as detected or not detected;

- 0142U – Infectious disease (bacteria and fungi), gram-negative bacterial identification and drug resistance element detection, dna (21 gram-negative bacterial targets, 6 resistance genes, 1 pan gram-positive bacterial target, 1 pan candida target), amplified probe technique, each target reported as detected or not detected;

- 0143U – Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service;

- 0144U – Drug assay, definitive, 160 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service;

- 0145U – Drug assay, definitive, 65 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service;

- 0146U – Drug assay, definitive, 80 or more drugs or metabolites, urine, by quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service;

- 0147U – Drug assay, definitive, 85 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service;

- 0148U – Drug assay, definitive, 100 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service;

- 0149U – Drug assay, definitive, 60 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring (mrm), with drug or metabolite description, comments including sample validation, per date of service;

- 0150U – Drug assay, definitive, 120 or more drugs or metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (lc-ms/ms) using multiple reaction monitoring

(mrm), with drug or metabolite description, comments including sample validation, per date of service;

- 0151U – Infectious disease (bacterial or viral respiratory tract infection), pathogen specific nucleic acid (dna or rna), 33 targets, real-time semi-quantitative pcr, bronchoalveolar lavage, sputum, or endotracheal aspirate, detection of 33 organismal and antibiotic resistance genes with limited semi-quantitative results;

- 0152U – Infectious disease (bacteria, fungi, parasites, and dna viruses), dna, pcr and next-generation sequencing, plasma, detection of]1,000 potential microbialorganisms for significant positive pathogens;

- 0153U – Oncology (breast), mrna, gene expression profiling by next-generation sequencing of 101 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a triple negative breast cancer clinical subtype(s) with information on immune cell involvement;

- 0154U – Fgfr3 (fibroblast growth factor receptor 3) gene analysis (ie, p.r248c [c.742c]t], p.s249c [c.746c]g], p.g370c [c.1108g]t], p.y373c [c.1118a]g], fgfr3-tacc3v1, and fgfr3-tacc3v3);

- 0155U – Pik3ca (phosphatidylinositol-4,5bisphosphate 3-kinase, catalytic subunit alpha) (eg, breast cancer) gene analysis (ie, p.c420r, p.e542k, p.e545a, p.e545d [g.1635g]t only], p.e545g, p.e545k, p.q546e, p.q546r, p.h1047l, p.h1047r, p.h1047y);

- 0157U – Apc (apc regulator of wnt signaling pathway) (eg, familial adenomatosis polyposis [fap]) mrna sequence analysis (list separately in addition to code for primary procedure);

- 0158U – Mlh1 (mutl homolog 1) (eg, hereditary non-polyposis colorectal cancer, lynch syndrome) mrna sequence analysis (list separately in addition to code for primary procedure);

- 0159U – Msh2 (muts homolog 2) (eg, hereditary colon cancer, lynch syndrome) mrna sequence analysis (list separately in addition to code for primary procedure);

- 0160U – Msh6 (muts homolog 6) (eg, hereditary colon cancer, lynch syndrome) mrna sequence analysis (list separately in addition to code for primary procedure);

- 0161U – Pms2 (pms1 homolog 2, mismatch repair system component) (eg, hereditary nonpolyposis colorectal cancer, lynch syndrome) mrna sequence analysis (list separately in addition to code for primary procedure); and

- 0162U – Hereditary colon cancer (lynch syndrome), targeted mrna sequence analysis panel (mlh1, msh2, msh6, pms2) (list separately in addition to code for primary procedure);

- 80145 - Measurement of adalimumab;

- 80187 - Measurement of posaconazole;
- 80230 – Measurement of infliximab;
- 80235 – Measurement of lacosamide;
- 80280 – Measurement of vedolizumab;
- 80285 - Measurement of voriconazole;
- 81277 - Cancer cytogenomic array gene analysis;
- 81307 – Gene analysis (partner and localizer of BRCA2) full sequence analysis;
- 81308 – Gene analysis (partner and localizer of BRCA2) for detection of known familial variant;
- 81309 – Gene analysis (partner and localizer of BRCA2) targeted sequence analysis;
- 81522 – mRNA gene expression analysis of 12 genes in breast tumor tissue;
- 81542 – mRNA gene expression analysis of 22 genes in prostate tumor tissue;
- 81552 – mRNA gene expression analysis of 15 genes in eye melanoma tissue or fine needle aspirate; and
- 87563 - Detection of Mycoplasma genitalium by DNA or RNA probe.

In addition, for 2020, there was 1 new HCPCS code, 0091U (Colorectal cancer screening by enumeration of tumor cells in blood), that was not mentioned in Transmittal 4326, CR 11280, Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment. The testing described by this code is subject to the CLIA regulations; however, it is not payable by Medicare in CY 2020. Hence, this new code was not included in this Change Request.

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	
11640.1	Contractors shall apply CLIA edits to the HCPCS codes mentioned above as subject to CLIA edits.		X						X	
11640.2	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							
11640.3	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							
11640.4	Contractors should 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		
11640.5	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.		X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"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