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Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment

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PROVIDER TYPE AFFECTED

This MLN Matters Article is for clinical diagnostic laboratories that submit claims to Medicare Administrative Contractors (MACs) for laboratory services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article informs laboratories of changes resulting from the quarterly update to the clinical laboratory fee schedule. Please be sure your billing staff is aware of these updates.

BACKGROUND

The quarterly updates are as follows:

Advanced Diagnostic Laboratory Tests (ADLTs)

Payment Amount for Specific Advanced Diagnostic Laboratory Tests (ADLTs)

- For dates of service beginning on or after April 1, 2020 through December 31, 2021, the payment amount for the ADLT DecisionDx-Melanoma™ is equal to $7,193.00. The fee schedule amount for DecisionDx-Melanoma™ reflects the weighted median of private payor rates for the test, as determined from applicable information collected and reported to the Centers for Medicare & Medicaid Services (CMS) during the new ADLT initial period. Once this ADLT is assigned its own unique HCPCS code, meaning one that describes only a single test, the HCPCS code and payment amount will be included on the CLFS file.
- Code 0090U – myPath Melanoma Effective September 6, 2019, CMS approved laboratory test myPath MelanomaTM, currently described by HCPCS code 0090U, as a new Advanced Diagnostic Laboratory Test (ADLT). The new ADLT initial period for myPath MelanomaTM is effective for dates of service beginning on or after October 1, 2019 through June 30, 2020. During the new ADLT initial period, payment for myPath MelanomaTM shall be made at actual list charge in the amount of $1,950, as described in the list of approved ADLTs, available at the following CLFS link: https://www.cms.gov/files/document/advanced-diagnostic-laboratory-tests-under-medicare-clfs.pdf. For dates of service beginning on or after July 1, 2020 through

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December 31, 2021, the payment rate for myPath MelanomaTM shall be equal to the weighted median of private payor rates established under the payment methodology described in 42 C.F.R. § 414.507(b) and in the amount of $1,755.

- Please refer to the following CMS website for additional information regarding these tests: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html#ADLT_tests.

Next Clinical Laboratory Fee Schedule (CLFS) Data Reporting Period for Clinical Diagnostic Laboratory Tests (CDLTs) — DELAYED

See MLN Matters Article MM12612 for more current information on this reporting period.

Section 1834A of the Act, as established by Section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for Clinical Diagnostic Laboratory Tests (CDLTs) under the CLFS. The CLFS final rule "Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule" (CMS-1621-F) was published in the Federal Register on June 23, 2016. The CLFS final rule implemented section 1834A of the Act. Under the CLFS final rule, reporting entities must report to CMS certain private payer rate information (applicable information) for their component applicable laboratories. The data collection period (the period where applicable information for an applicable laboratory is obtained from claims for which the laboratory received final payment during the period) was from January 1, 2019 through June 30, 2019.

Section 105 (a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116-94, enacted December 19, 2019) and Section 3718 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (Pub. L. 116-136, enacted March 27, 2020) made several revisions to the next data reporting period for CDLTs that are not Advanced Diagnostic Laboratory Tests (ADLTs) and the phase-in of payment reductions under the Medicare private payor rate-based CLFS. In summary, revisions are:

- The next data reporting period of January 1, 2022, through March 31, 2022, will be based on the original data collection period of January 1, 2019, through June 30, 2019.
- After the next data reporting period, there is a three-year data reporting cycle for CDLTs that are not ADLTs, (that is 2025, 2028, etc.).
- The statutory phase-in of payment reductions resulting from private payor rate implementation is extended through CY 2024. There is a 0.0 percent reduction for CY 2021, and payment may not be reduced by more than 15 percent for CYs 2022 through 2024.

Coronavirus-19 (COVID-19) Policy Updates

- **Payment for Specimen Collection for Purposes of COVID-19 Testing**

  For the duration of the Public Health Emergency (PHE) for the COVID-19 pandemic and in an effort to be as expansive as possible within the current authorities to have diagnostic testing available to Medicare beneficiaries who need it, in the interim final rule with comment period (IFC), CMS-1744-IFC, Medicare and Medicaid Programs; Policy and Regulatory

Revisions in Response to the COVID-19 Public Health Emergency, CMS changed the Medicare payment rules to provide payment to independent laboratories for specimen collection from beneficiaries who are homebound or inpatients not in a hospital for COVID-19 testing under certain circumstances. For more information on this policy update, please refer to https://www.cms.gov/files/document/covid-final-ifc.pdf.

- **Revisions to Ordering Requirements for Clinical Laboratory Diagnostic Testing**

  In the interim final rule with comment period, CMS-5531-IFC, Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program, on an interim basis for the duration of the PHE for the COVID-19 pandemic, CMS removed the requirement that certain CDLTs must be ordered by a treating physician or Non-Physician Practitioner (NPP). This will allow any healthcare professional authorized to do so under State law to order COVID-19 diagnostic laboratory tests (including serological and antibody tests). Because the symptoms for coronavirus, influenza and Respiratory Syncytial Virus (RSV) are often the same, such that concurrent testing for all three viruses is warranted, this interim policy also applies to influenza and RSV tests, but only when they are furnished in conjunction with a medically necessary COVID-19 diagnostic laboratory test to establish or rule out a COVID-19 diagnosis or identify an adaptive immune response to SARS-COV-2. For more information on this policy update, please refer to https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.pdf.

- **Coverage of COVID-19 Serology Testing**

  In the interim final rule with comment period, CMS-5531-IFC, CMS finalized on an interim basis, that during the PHE for the COVID-19 pandemic, Medicare will cover FDA-authorized COVID-19 serology tests as they are reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act (the Act) for beneficiaries with known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection. CMS amended Section 410.32(a)(3) of the Code of Federal Regulations to reflect this determination of coverage. For more information on this policy update, please refer to https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.pdf.

- **High Throughput Technologies**

  CMS issued CMS Ruling CMS-2020-01-R concerning payment under Medicare Supplementary Medical Insurance (Part B) of certain CDLTs for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19 making use of high throughput technologies. As described in CMS Ruling CMS 2020-01-R, a high throughput technology uses a platform that employs automated processing of more than two hundred specimens a day. For more information on this policy update, please refer to https://www.cms.gov/files/document/cms-2020-01-r.pdf.

Clinical Laboratory Fee Schedule Beginning January 1, 2018

- Effective January 1, 2018, CLFS rates are based on weighted median private payor rates as required by the Protecting Access to Medicare Act (PAMA) of 2014.

- The Part B deductible and coinsurance do not apply for services paid under the CLFS'
- For more details, visit PAMA Regulations, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.
- **Access to Data File:** Internet access to the quarterly CLFS data file will be available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/index.html. Other interested parties, such as the Medicaid State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, may retrieve the quarterly clinical laboratory fee schedule. It will be available in multiple formats: Excel, text, and comma delimited.
- **Pricing Information:** The CLFS includes separately payable fees for certain specimen collection methods (codes 36415, P9612, and P9615). The fees are established in accordance with Section 1833(h)(4)(B) of the Act. Also note additional specimen collection codes below during the PHE.

Codes Effective June 25, 2020

Please note that since the issuing of CR 11815, Quarterly Update for Clinical Laboratory Fee Schedule and Laboratory Services Subject to Reasonable Charge Payment, (see the related MLN Matters article at https://www.cms.gov/files/document/mm11815.pdf) the following codes were added to the national HCPCS file with an effective date of June 25, 2020. The codes are contractor-priced until they are nationally priced and undergo the CLFS annual payment determination process in accordance with Sections 1833(h)(8), 1834A(c) and 1834(A)(f) of the Act.

1. **Code:87426**
   - Long Descriptor: Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV, SARS-CoV-2 [COVID-19])
   - Short Descriptor: CORONAVIRUS AG IA
   - Type of Service (TOS): 5

2. **Code: 0223U**
   - Laboratory Name: QIAstat-Dx Respiratory SARS CoV-2 Panel, QIAGEN Sciences, QIAGEN GmbH
   - Long Descriptor: Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
   - Short Descriptor: NFCT DS 22 TRGT SARS-COV-2
   - TOS: 5

3. **Code: 0224 U**

- Laboratory Name: COVID-19 Antibody Test, Mt Sinai, Mount Sinai Laboratory
- Long Descriptor: Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed
- Short Descriptor: ANTIBODY SARS-COV-2 TITER(S)
- TOS: 5

Codes Effective August 10, 2020

The listed new codes will be added to the national HCPCS file with an effective date of August 10, 2020 and do not need to be manually added to the HCPCS files by the MACs. However, these new codes are contractor-priced (where applicable) until they are nationally priced and undergo the CLFS annual payment determination process in accordance with the Social Security Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f). MACs shall only price PLA codes for laboratories within their jurisdiction.

1. **Code: 86408**
   - Long Descriptor: Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); screen
   - Short Descriptor: NEUTRLZG ANTB SARSCOV2 SCR
   - TOS: 5
2. **Code: 86409**
   - Long Descriptor: Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]); titer
   - Short Descriptor: NEUTRLZG ANTB SARSCOV2 TITER
   - TOS: 5
3. **Code: 0225U**
   - Laboratory Name: ePlex® Respiratory Pathogen Panel 2, GenMark Dx, GenMark Diagnostics, Inc
   - Long Descriptor: Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
   - Short Descriptor: NFCT DS DNA&RNA 21 SARSCOV2
   - TOS: 5
4. **Code: 0226U**
   - Laboratory Name: Tru-ImmuneTM, Ethos Laboratories, GenScript® USA Inc
   - Long Descriptor: Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), ELISA, plasma, serum
   - Short Descriptor: SVNT SARSCOV2 ELISA PLSM SRM
   - TOS: 5

Code Effective September 8, 2020

The listed new code will be added to the national HCPCS file with an effective date of September 8, 2020 and does not need to be manually added to the HCPCS files by the MACs. However, the new code is contractor-priced (where applicable) until it is nationally priced and undergoes the CLFS annual payment determination process in accordance with the Social Security Act § 1833(h)(8), § 1834A(c) and § 1834(A)(f).

- Code: 86413
- Long Descriptor: Severe acute respiratory syndrome coronavirus 2 (SARSCoV-2) (Coronavirus disease [COVID-19]) antibody,quantitative
- Short Descriptor: SARS-COV-2 ANTB QUANTITATIVE
- TOS: 5

New Codes Effective October 1, 2020

These listed new codes will be added to the national HCPCS file with an effective date of October 1, 2020. These new codes are contractor-priced (where applicable) until they are nationally priced and undergo the CLFS annual payment determination process in accordance with the Social Security Act §1833(h)(8), §1834A(c) and §1834(A)(f).

1. **Code: 0015M**
   - Long Descriptor: Adrenal cortical tumor, biochemical assay of 25 steroid markers, utilizing 24-hour urine specimen and clinical parameters, prognostic algorithm reported as a clinical risk and integrated clinical steroid risk for adrenal cortical carcinoma, adenoma, or other adrenal malignancy
   - Short Descriptor: ADRNL CORTCL TUM BCHM ASY 25
   - TOS: 5

2. **Code: 0016M**
   - Long Descriptor: Oncology (bladder), mRNA, microarray gene expression profiling of 209 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as molecular subtype (luminal, luminal infiltrated, basal, basal claudin-low, neuroendocrine-like)
   - Short Descriptor: ONC BLADDER MRNA 209 GEN ALG
   - TOS: 5

New Codes Effective October 1, 2020

Proprietary Laboratory Analysis (PLAs)

The new codes in Table 1 below have been added to the national HCPCS file with an effective date of October 1, 2020. These new codes are contractor-priced (where applicable) until they are nationally priced and undergo the CLFS annual payment determination process in accordance with Sections 1833(h)(8), 1834A(c) and 1834(A)(f) of the Act. The table includes the laboratory, long descriptor, and short descriptor of each new code. The type of service code for

all HCPCS in the table is 5.

Table 1 - New Codes Effective October 1, 2020

Laboratory	CPT Code	Long Descriptor	Short Descriptor
PredictSURE IBDTM Test, KSL Diagnostics, PredictImmune Ltd	0203U	Autoimmune (inflammatory bowel disease), mRNA, gene expression profiling by quantitative RT-PCR, 17 genes (15 target and 2 reference genes), whole blood, reported as a continuous risk score and classification of inflammatory bowel disease aggressiveness	AI IBD MRNA XPRSN PRFL 17
Afirma Xpression Atlas, Veracyte, Inc, Veracyte, Inc	0204U	Oncology (thyroid), mRNA, gene expression analysis of 593 genes (including BRAF, RAS, RET, PAX8, and NTRK) for sequence variants and rearrangements, utilizing fine needle aspirate, reported as detected or not detected	ONC THYR MRNA XPRSN ALYS 593
Vita Risk®, Arctic Medical Laboratories, Arctic Medical Laboratories	0205U	Ophthalmology (age-related macular degeneration), analysis of 3 gene variants (2 CFH gene, 1 ARMS2 gene), using PCR and MALDI-TOF, buccal swab, reported as positive or negative for neovascular age-related macular-degeneration risk associated with zinc supplements	OPH AMD ALYS 3 GENE VARIANTS
DISCERNTM, NeuroDiagnostics, NeuroDiagnostics	0206U	Neurology (Alzheimer disease); cell aggregation using morphometric imaging and protein kinase C-epsilon (PKCe) concentration in response to amylospheroid treatment by ELISA, cultured skin fibroblasts, each reported as positive or negative for Alzheimer disease	NEURO ALZHEIMER CELL AGGREGJ
DISCERNTM, NeuroDiagnostics, NeuroDiagnostics	0207U	disease quantitative imaging of phosphorylated ERK1 and ERK2 in response to bradykinin treatment by in situ immunofluorescence, using cultured skin fibroblasts, reported as a probability index for Alzheimer disease (List separately in addition to code for primary procedure)	NEURO ALZHEIMER QUAN IMAGING
Afirma Medullary Thyroid Carcinoma (MTC) Classifier, Veracyte, Inc, Veracyte, Inc	0208U	Oncology (medullary thyroid carcinoma), mRNA, gene expression analysis of 108 genes, utilizing fine needle aspirate, algorithm reported as positive or negative for medullary thyroid carcinoma	ONC MTC MRNA XPRSN ALYS 108

Laboratory	CPT Code	Long Descriptor	Short Descriptor
CNGnomeTM, PerkinElmer Genomics, PerkinElmer Genomics	0209U	Cytogenomic constitutional (genome-wide) analysis, interrogation of genomic regions for copy number, structural changes and areas of homozygosity for chromosomal abnormalities	CYTOG CONST ALYS INTERROG
BioPlex 2200 RPR Assay - Quantitative, Bio-Rad Laboratories, Bio-Rad Laboratories	0210U	Syphilis test, non-treponemal antibody, immunoassay, quantitative (RPR)	SYPHILIS TST ANTB IA QUAN
MI Cancer SeekTM - NGS Analysis, Caris MPI d/b/a Caris Life Sciences, Caris MPI d/b/a Caris Life Sciences	0211U	Oncology (pan-tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded tissue, interpretative report for single nucleotide variants, copy number alterations, tumor mutational burden, and microsatellite instability, with therapy association	ONC PAN-TUM DNA&RNA GNRJ SEQ
Genomic Unity® Whole Genome Analysis – Proband, Variantyx Inc, Variantyx Inc	0212U	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband	RARE DS GEN DNA ALYS PROBAND
Genomic Unity® Whole Genome Analysis - Comparator, Variantyx Inc, Variantyx Inc	0213U	Rare diseases (constitutional/heritable disorders), whole genome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator genome (eg, parent, sibling)	RARE DS GEN DNA ALYS EA COMP

Laboratory	CPT Code	Long Descriptor	Short Descriptor
Genomic Unity® Exome Plus Analysis - Proband, Variantyx Inc, Variantyx Inc	0214U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, proband	RARE DS XOM DNA ALYS PROBAND
Genomic Unity® Exome Plus Analysis - Comparator, Variantyx Inc, Variantyx Inc	0215U	Rare diseases (constitutional/heritable disorders), whole exome and mitochondrial DNA sequence analysis, including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants, each comparator exome (eg, parent, sibling)	RARE DS XOM DNA ALYS EA COMP
Genomic Unity® Ataxia Repeat Expansion and Sequence Analysis, Variantyx Inc, Variantyx Inc	0216U	Neurology (inherited ataxias), genomic DNA sequence analysis of 12 common genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants	NEURO INH ATAXIA DNA 12 COM
Genomic Unity® Comprehensive Ataxia Repeat Expansion and Sequence Analysis, Variantyx Inc, Variantyx Inc	0217U	Neurology (inherited ataxias), genomic DNA sequence analysis of 51 genes including small sequence changes, deletions, duplications, short tandem repeat gene expansions, and variants in non-uniquely mappable regions, blood or saliva, identification and categorization of genetic variants	NEURO INH ATAXIA DNA 51 GENE
Genomic Unity® DMD Analysis, Variantyx Inc, Variantyx Inc	0218U	Neurology (muscular dystrophy), DMD gene sequence analysis, including small sequence changes, deletions, duplications, and variants in non-uniquely mappable regions, blood or saliva, identification and characterization of genetic variants	NEURO MUSC DYS DMD SEQ ALYS

Laboratory	CPT Code	Long Descriptor	Short Descriptor
Sentosa® SQ HIV-1 Genotyping Assay, Vela Diagnostics USA, Inc, Vela Operations Singapore Pte Ltd	0219U	Infectious agent (human immunodeficiency virus), targeted viral next-generation sequence analysis (ie, protease [PR], reverse transcriptase [RT], integrase [INT]), algorithm reported as prediction of antiviral drug susceptibility	NFCT AGT HIV GNRJ SEQ ALYS
PreciseDxTM Breast Cancer Test, PreciseDx, PreciseDx	0220U	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score	ONC BRST CA AI ASSMT 12 FEAT
Navigator ABO Blood Group NGS, Grifols Immunohematology Center, Grifols Immunohematology Center	0221U	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis, next-generation sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene	ABO GNOTYP NEXT GNRJ SEQ ABO
Navigator Rh Blood Group NGS, Grifols Immunohematology Center, Grifols Immunohematology Center	0222U	Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis, next-generation sequencing, RH proximal promoter, exons 1-10, portions of introns 2-3	RHD&RHCE GNTYP NEXT GNRJ SEQ

ADDITIONAL INFORMATION

The official instruction, CR 11937, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/r10367CP.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
March 22, 2022	We revised this Article to add a link to Article MM12612, which has current information on the Next CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests. All other information is the same.
September 24, 2020	We revised the article to add a new COVID 19 code (86413) and ADLT code (0090U). Also, we revised the CR release date, transmittal number, and web address of the CR. All other information remains the same.
August 24, 2020	We revised this article to reflect an updated CR 11937 that includes additional COVID-19 codes 86408, 86409, 0225U and 0226U, effective August 10, 2020. CR 11937 also added codes 0015M and 0016M, effective October 1, 2020. The CR release date, transmittal number and link to the transmittal also changed.
August 7, 2020	Initial article released.