

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10988	Date: September 10, 2021
	Change Request 12435

SUBJECT: Quarterly Update for Clinical Laboratory Fee Schedule (CLFS) and Laboratory Services Subject to Reasonable Charge Payment

I. SUMMARY OF CHANGES: This Recurring Update Notification (RUN) provides instructions for the quarterly update to the clinical laboratory fee schedule. This RUN applies to chapter 16, section 20.

EFFECTIVE DATE: October 1, 2021

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: October 4, 2021

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

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EFFECTIVE DATE: October 1, 2021

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IMPLEMENTATION DATE: October 4, 2021

I. GENERAL INFORMATION

A. Background: This Recurring Update Notification (RUN) provides instructions for the quarterly update to the clinical laboratory fee schedule. This RUN applies to chapter 16, section 20.

B. Policy: Clinical Laboratory Fee Schedule

Advanced Diagnostic Laboratory Tests (ADLTs)

- 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 CLFS Data Reporting Period for Clinical Diagnostic Laboratory Tests

- 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.
- 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, that is, 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.

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 clinical laboratory fee schedule.

Number	Requirement	Responsibility										
		A/B MAC		H H H	D M E M A C	Shared- System Maintainers				Other		
		A	B			F I S S	M C S	V M S	C W F			
12435.2.3	Contractors shall address any questions/concerns regarding the content of the files and/or specific HCPCS codes contained within by emailing CLFS_Inquiries@cms.hhs.gov.	X	X									VDC
12435.3	A/B MAC Part B contractors shall determine the reasonable charge for the codes identified as paid under the reasonable charge basis (**NOTE** - This requirement is applicable to the January quarterly release CR only).		X									
12435.4	A/B MAC Part A contractors shall determine payment on a reasonable cost basis when these services are performed for hospital-based renal dialysis facility patients (**NOTE** - This requirement is applicable to the January quarterly release CR only).	X										
12435.5	Contractors shall be aware of any new Advanced Diagnostic Laboratory Test (ADLT) codes, and/or CPT/HCPCS codes (including their TOS designation(s) and Effective date), and/or any deleted/terminated codes as applicable listed in this Change Request and shall update their systems as necessary to accept/delete/terminate them.	X	X								X	
12435.5.1	In instances where Medicare covered CLFS procedure codes do not yet appear on the quarterly CLFS file or the quarterly Integrated Outpatient Code Editor (IOCE) update, contractors shall locally price the codes until they appear on the CLFS file and/or, for Part A claims, the IOCE.	X	X									
12435.6	Contractors shall not search their files to either retract payment or retroactively pay claims; however, contractors should adjust claims if they are brought to their attention.	X	X									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E D I	C M E D I
		A	B	H H H		
12435.7	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	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): Laura Ashbaugh, 410-786-1113 or laura.ashbaugh2@cms.hhs.gov , Glenn McGuirk, 410-786-5723 or Glenn.McGuirk@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: 1

New Codes Effective October 1, 2021

Proprietary Laboratory Analysis (PLAs)

The following new codes have been added to the national HCPCS file with an effective date of October 1, 2021 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.

Laboratory	CPT Code	Long Descriptor	Short Descriptor	TOS	Effective Date
Cap-Score™ Test, Androvia LifeSciences, Avantor Clinical Services (previously known as Therapak)	0255U	Andrology (infertility), sperm-capacitation assessment of ganglioside GM1 distribution patterns, fluorescence microscopy, fresh or frozen specimen, reported as percentage of capacitated sperm and probability of generating a pregnancy score	ANDROLOGY INFERTILITY ASSMT	5	10/01/21
Trimethylamine (TMA) and TMA N-Oxide, Children's Hospital Colorado Laboratory	0256U	Trimethylamine/trimethylamine N-oxide (TMA/TMAO) profile, tandem mass spectrometry (MS/MS), urine, with algorithmic analysis and interpretive report	TMA/TMAO PRFL MS/MS UR ALG	5	10/01/21
Very-Long Chain Acyl-CoA Dehydrogenase (VLCAD) Enzyme Activity, Children's Hospital Colorado Laboratory	0257U	Very long chain acyl-coenzyme A (CoA) dehydrogenase (VLCAD), leukocyte enzyme activity, whole blood	VLCAD LEUK NZM ACTV WHL BLD	5	10/01/21
Mind.Px, Mindera, Mindera Corporation	0258U	Autoimmune (psoriasis), mRNA, next-generation sequencing, gene expression profiling of 50-100 genes, skin-surface collection using adhesive patch, algorithm reported as likelihood of response to psoriasis biologics	AI PSOR MRNA 50-100 GEN ALG	5	10/01/21
GFR by NMR, Labtech™ Diagnostics	0259U	Nephrology (chronic kidney disease), nuclear magnetic resonance spectroscopy measurement of myo-inositol, valine, and creatinine, algorithmically combined with cystatin C (by immunoassay) and demographic data to determine estimated glomerular filtration rate (GFR), serum, quantitative	NEPH CKD NUC MRS MEAS GFR	5	10/01/21
Augusta Optical Genome Mapping, Georgia Esoteric and Molecular (GEM) Laboratory, LLC, Bionano Genomics Inc	0260U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping	RARE DS ID OPT GENOME MAPG	5	10/01/21
Immunoscore®, HailoDx, HailoDx	0261U	Oncology (colorectal cancer), image analysis with artificial intelligence assessment of 4 histologic and immunohistochemical features (CD3 and CD8 within tumor-stroma border and tumor core), tissue, reported as immune response and recurrence-risk score	ONC CLRCT CA IMG ALYS W/AI	5	10/01/21
OncoSignal 7 Pathway Signal, Protean BioDiagnostics, Philips Electronics Nederland BV	0262U	Oncology (solid tumor), gene expression profiling by real-time RT-PCR of 7 gene pathways (ER, AR, P13K, MAPK, HH, TGFB, Notch), formalin-fixed paraffin-embedded (FFPE), algorithm reported as gene pathway activity score	ONC SLD TUM RTPCR 7 GEN	5	10/01/21
NPDX ASD and Central Carbon Energy Metabolism, Stemina Biomarker Discovery, Inc, Stemina Biomarker Discovery, Inc	0263U	Neurology (autism spectrum disorder [ASD]), quantitative measurements of 16 central carbon metabolites (ie, α-ketoglutarate, alanine, lactate, phenylalanine, pyruvate, succinate, carnitine, citrate, fumarate, hypoxanthine, inosine, malate, S-sulfocysteine, taurine, urate, and xanthine), liquid chromatography tandem mass spectrometry (LC-MS/MS), plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)	NEURO ASD MEAS 16 C METBLT	5	10/01/21
Praxis Optical Genome Mapping, Praxis Genomics LLC	0264U	Rare diseases (constitutional/heritable disorders), identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping	RARE DS ID OPT GENOME MAPG	5	10/01/21
Praxis Whole Genome Sequencing, Praxis Genomics LLC	0265U	Rare constitutional and other heritable disorders, whole genome and mitochondrial DNA sequence analysis, blood, frozen and formalin-fixed paraffin-embedded (FFPE) tissue, saliva, buccal swabs or cell lines, identification of single nucleotide and copy number variants	RAR DO WHL GN&MTCRDL DNA ALS	5	10/01/21
Praxis Transcriptome, Praxis Genomics LLC	0266U	Unexplained constitutional or other heritable disorders or syndromes, tissue-specific gene expression by whole-transcriptome and next-generation sequencing, blood, formalin-fixed paraffin-embedded (FFPE) tissue or fresh frozen tissue, reported as presence or absence of splicing or expression changes	UNXPL CNST HRTBL DO GN XPRSN	5	10/01/21
Praxis Combined Whole Genome Sequencing and Optical Genome Mapping, Praxis Genomics LLC	0267U	Rare constitutional and other heritable disorders, identification of copy number variations, inversions, insertions, translocations, and other structural variants by optical genome mapping and whole genome sequencing	RARE DO ID OPT GEN MAPG&SEQ	5	10/01/21
Versiti™ aHUS Genetic Evaluation, Versiti™ Diagnostic Laboratories, Versiti™	0268U	Hematology (atypical hemolytic uremic syndrome [aHUS]), genomic sequence analysis of 15 genes, blood, buccal swab, or amniotic fluid	HEM AHUS GEN SEQ ALYS 15 GEN	5	10/01/21
Versiti™ Autosomal Dominant Thrombocytopenia Panel, Versiti™ Diagnostic Laboratories, Versiti™	0269U	Hematology (autosomal dominant congenital thrombocytopenia), genomic sequence analysis of 14 genes, blood, buccal swab, or amniotic fluid	HEM AUT DM CGEN TRMBCTPNA 14	5	10/01/21
Versiti™ Coagulation Disorder Panel, Versiti™ Diagnostic Laboratories, Versiti™	0270U	Hematology (congenital coagulation disorders), genomic sequence analysis of 20 genes, blood, buccal swab, or amniotic fluid	HEM CGEN COAGJ DO 20 GENES	5	10/01/21
Versiti™ Congenital Neutropenia Panel, Versiti™ Diagnostic Laboratories, Versiti™	0271U	Hematology (congenital neutropenia), genomic sequence analysis of 23 genes, blood, buccal swab, or amniotic fluid	HEM CGEN NEUTROPENIA 23 GEN	5	10/01/21
Versiti™ Comprehensive Bleeding Disorder Panel, Versiti™ Diagnostic Laboratories, Versiti™	0272U	Hematology (genetic bleeding disorders), genomic sequence analysis of 51 genes, blood, buccal swab, or amniotic fluid, comprehensive	HEM GENETIC BLD DO 51 GENES	5	10/01/21
Versiti™ Fibrinolytic Disorder Panel, Versiti™ Diagnostic Laboratories, Versiti™	0273U	Hematology (genetic hyperfibrinolysis, delayed bleeding), genomic sequence analysis of 8 genes (F13A1, F13B, FGA, FGB, FGG, SERPINA1, SERPINE1, SERPINF2, LAU), blood, buccal swab, or amniotic fluid	HEM GEN HYPRFIBRNLYSIS 8 GEN	5	10/01/21
Versiti™ Comprehensive Platelet Disorder Panel, Versiti™ Diagnostic Laboratories, Versiti™	0274U	Hematology (genetic platelet disorders), genomic sequence analysis of 43 genes, blood, buccal swab, or amniotic fluid	HEM GEN PLTLT DO 43 GENES	5	10/01/21

Versiti™ Heparin-Induced Thrombocytopenia Evaluation – PEA, Versiti™ Diagnostic Laboratories, Versiti™	0275U	Hematology (heparin-induced thrombocytopenia), platelet antibody reactivity by flow cytometry, serum	HEM HEPRN NDUC TRMBCTPNA SRM	5	10/01/21
Versiti™ Inherited Thrombocytopenia Panel, Versiti™ Diagnostic Laboratories, Versiti™	0276U	Hematology (inherited thrombocytopenia), genomic sequence analysis of 23 genes, blood, buccal swab, or amniotic fluid	HEM INH THROMBOCYTOPENIA 23	5	10/01/21
Versiti™ Platelet Function Disorder Panel, Versiti™ Diagnostic Laboratories, Versiti™	0277U	Hematology (genetic platelet function disorder), genomic sequence analysis of 31 genes, blood, buccal swab, or amniotic fluid	HEM GEN PLTLT FUNCJ DO 31	5	10/01/21
Versiti™ Thrombosis Panel, Versiti™ Diagnostic Laboratories, Versiti™	0278U	Hematology (genetic thrombosis), genomic sequence analysis of 12 genes, blood, buccal swab, or amniotic fluid	HEM GEN THROMBOSIS 12 GENES	5	10/01/21
Versiti™ VWF Collagen III Binding, Versiti™ Diagnostic Laboratories, Versiti™	0279U	Hematology (von Willebrand disease [VWD]), von Willebrand factor (VWF) and collagen III binding by enzyme-linked immunosorbent assays (ELISA), plasma, report of collagen III binding	HEM VW FACTOR&CLGN III BNDG	5	10/01/21
Versiti™ VWF Collagen IV Binding, Versiti™ Diagnostic Laboratories, Versiti™	0280U	Hematology (von Willebrand disease [VWD]), von Willebrand factor (VWF) and collagen IV binding by enzyme-linked immunosorbent assays (ELISA), plasma, report of collagen IV binding	HEM VW FACTOR&CLGN IV BNDG	5	10/01/21
Versiti™ VWF Propeptide Antigen, Versiti™ Diagnostic Laboratories, Versiti™	0281U	Hematology (von Willebrand disease [VWD]), von Willebrand propeptide, enzyme-linked immunosorbent assays (ELISA), plasma, diagnostic report of von Willebrand factor (VWF) propeptide antigen level	HEM VWD PROPEPTIDE AG LVL	5	10/01/21
Versiti™ Red Cell Genotyping Panel, Versiti™ Diagnostic Laboratories, Versiti™	0282U	Red blood cell antigen typing, DNA, genotyping of 12 blood group system genes to predict 44 red blood cell antigen phenotypes	RBC DNA GNTYP 12 BLD GRP GEN	5	10/01/21
Versiti™ VWD Type 2B Evaluation, Versiti™ Diagnostic Laboratories, Versiti™	0283U	von Willebrand factor (VWF), type 2B, platelet-binding evaluation, radioimmunoassay, plasma	VW FACTOR TYPE 2B EVAL PLSM	5	10/01/21
Versiti™ VWD Type 2N Binding, Versiti™ Diagnostic Laboratories, Versiti™	0284U	von Willebrand factor (VWF), type 2N, factor VIII and VWF binding evaluation, enzyme-linked immunosorbent assays (ELISA), plasma	VW FACTOR TYPE 2N EVAL PLSM	5	10/01/21