



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

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Related Change Request (CR) Number: 10875

Related CR Release Date: July 20, 2018

Effective Date: October 1, 2018

Related CR Transmittal Number: R4090CP

Implementation Date: October 1, 2018

PROVIDER TYPE AFFECTED

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

PROVIDER ACTION NEEDED

Change Request (CR) 10875 provides instructions for the quarterly update to the Clinical Laboratory Fee Schedule (CLFS). These updates apply to Chapter 16, Section 20 of the Medicare Claims Processing Manual. Please make sure your billing staffs are aware of these updates.

BACKGROUND

Effective January 1, 2018, CLFS rates will be based on weighted median private payer rates as required by the Protecting Access to Medicare Act (PAMA) of 2014. For more details, the PAMA regulations are available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html>.

Note: Part B deductible and coinsurance do not apply for services paid under the CLFS.

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 Medicare State agencies, the Indian Health Service, the United Mine Workers, and the Railroad Retirement Board, will use the Internet to retrieve the quarterly CLFS. It will be available in Excel, text, and comma delimited formats.

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 Social Security Act.

New Codes

The following new codes will be contractor-priced, until they are addressed at the annual Clinical Laboratory Public Meeting, which will take place in July 2018. The following "U" codes will have Healthcare Common Procedure Coding System (HCPCS) Pricing Indicator Code – 22: Price established by A/B MACs Part B (for example, gap-fills, A/B MACs Part B established panels) instead of Pricing Indicator – 21: Price Subject to National Limitation Amount. (Code, Long Descriptor, Short Descriptor, Effective Date, Type of Service (TOS)).

These new codes are effective July 1, 2018

- 0045U TOS 5; Short Descriptor—ONC BRST DUX CARC IS 12 GENE; Long Descriptor—Oncology (breast ductal carcinoma in situ), mRNA, gene expression profiling by real-time RT-PCR of 12 genes (7 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as recurrence score
- 0046U TOS 5; Short Descriptor—FLT3 GENE ITD VARIANTS QUAN; Long Descriptor—FLT3 (fms-related tyrosine kinase 3) (e.g., acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative
- 0047U TOS 5; Short Descriptor—ONC PRST8 MRNA 17 GENE ALG; Long Descriptor—Oncology (prostate), mRNA, gene expression profiling by real-time RT-PCR of 17 genes (12 content and 5 housekeeping), utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a risk score
- 0048U TOS 5; Short Descriptor—ONC SLD ORG NEO DNA 468 GENE; Long Descriptor—Oncology (solid organ neoplasia), DNA, targeted sequencing of protein-coding exons of 468 cancer-associated genes, including interrogation for somatic mutations and microsatellite instability, matched with normal specimens, utilizing formalin-fixed paraffin-embedded tumor tissue, report of clinically significant mutation(s)
- 0049U TOS 5; Short Descriptor—NPM1 GENE ANALYSIS QUAN; Long Descriptor—NPM1 (nucleophosmin) (e.g., acute myeloid leukemia) gene analysis, quantitative
- 0050U TOS 5; Short Descriptor—TRGT GEN SEQ DNA 194 GENES; Long Descriptor—Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements
- 0051U TOS 5; Short Descriptor—RX MNTR LC-MS/MS UR 31 PNL; Long Descriptor—Prescription drug monitoring, evaluation of drugs present by LC-MS/MS, urine, 31 drug panel, reported as quantitative results, detected or not detected, per date of service
- 0052U TOS 5; Short Descriptor—LPOPRTN BLD W/5 MAJ CLASSES; Long Descriptor—Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation
- 0053U TOS 5; Short Descriptor—ONC PRST8 CA FISH ALYS 4 GEN; Long Descriptor—Oncology (prostate cancer), FISH analysis of 4 genes (ASAP1, HDAC9,

CHD1 and PTEN), needle biopsy specimen, algorithm reported as probability of higher tumor grade

- 0054U TOS 5; Short Descriptor—RX MNTR 14+ DRUGS & SBSTS; Long Descriptor—Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service
- 0055U TOS 5; Short Descriptor—CARD HRT TRNSPL 96 DNA SEQ; Long Descriptor—Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma
- 0056U TOS 5; Short Descriptor—HEM AML DNA GENE REARGMT; Long Descriptor—Hematology (acute myelogenous leukemia), DNA, whole genome next-generation sequencing to detect gene rearrangement(s), blood or bone marrow, report of specific gene rearrangement(s)
- 0057U TOS 5; Short Descriptor—ONC SLD ORG NEO MRNA 51 GENE; Long Descriptor—Oncology (solid organ neoplasia), mRNA, gene expression profiling by massively parallel sequencing for analysis of 51 genes, utilizing formalin-fixed paraffin-embedded tissue, algorithm reported as a normalized percentile rank
- 0058U TOS 5; Short Descriptor—ONC MERKEL CLL CARC SRM QUAN; Long Descriptor—Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative
- 0059U TOS 5; Short Descriptor—ONC MERKEL CLL CARC SRM +/-; Long Descriptor—Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative
- 0060U TOS 5; Short Descriptor—TWN ZYG GEN SEQ ALYS CHRMS2; Long Descriptor—Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood
- 0061U TOS 5; Short Descriptor—TC MEAS 5 BMRK SFDI M-S ALYS; Long Descriptor—Transcutaneous measurement of five biomarkers (tissue oxygenation [StO₂], oxyhemoglobin [ctHbO₂], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging)

This following existing code are revised, effective July 1, 2018:

- 0006U TOS 5; Short Descriptor—DETC IA MEDS 120+ ANALYTES; Long Descriptor—Detection of interacting medications, substances, supplements and foods, 120 or more analytes, definitive chromatography with mass spectrometry, urine, description and severity of each interaction identified per date of service

This following existing code is approved as an Advanced Diagnostic Laboratory Test (ADLT)

and was added to the CLFS effective July 1, 2018:

- 0037U TOS 5; Short Descriptor—Trgt gen seq dna 324 genes; Long Descriptor— Targeted genomic sequence analysis, solid organ neoplasm, DNA analysis of 324 genes, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability and tumor mutational burden

Note: MACs will not search their files to either retract payment or retroactively pay claims. However, MACs should adjust claims if they are brought to their attention.

ADDITIONAL INFORMATION

The official instruction, CR 10875, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4090CP.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
July 20, 2018	Initial article released.

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