



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

MLN Matters Number: MM10642

Related Change Request (CR) Number: 10642

Related CR Release Date: May 11, 2018

Effective Date: July 1, 2018

Related CR Transmittal Number: R4045CP

Implementation Date: July 2, 2018

### PROVIDER TYPE AFFECTED

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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

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Change Request (CR) 10642 informs MACs about the changes in the July 2018 quarterly update to the Clinical Laboratory Fee Schedule (CLFS). Make sure that your billing staffs are aware of these changes.

### BACKGROUND

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Effective January 1, 2018, CLFS rates will be based on weighted median private payor rates as required by the Protecting Access to Medicare Act (PAMA) of 2014. For more details, visit PAMA Regulations, at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html>. Part B deductible and coinsurance do not apply for services paid under the clinical laboratory fee schedule.

#### Access to Data File

Under normal circumstances, CMS will make the updated CLFS data file available to MACs approximately 6 weeks prior to the beginning of each quarter. For example, the updated file will typically be made available for download and testing on or before approximately May 15 for the July 1 release. 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, should use the Internet to retrieve the

quarterly CLFS. 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 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 HCPCS Pricing Indicator Code - 22 = Price established by A/B MACs Part B (e.g., gap-fills, A/B MACs Part B established panels) instead of Pricing Indicator - 21 = Price Subject to National Limitation Amount. (Code, Type of Service (TOS), Short Descriptor, Long Descriptor)

The following new codes are effective April 1, 2018:

- 0035U TOS 5; Short Descriptor—Neuro csf prion prtn qual; Long Descriptor—Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion, qualitative
- 0036U TOS 5; Short Descriptor—Xome tum & nml spec seq alys; Long Descriptor—Exome (ie, somatic mutations), paired formalin-fixed paraffin-embedded tumor tissue and normal specimen, sequence analyses
- 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
- 0038U TOS 5; Short Descriptor—Vitamin d srm microsamp quan; Long Descriptor—Vitamin D, 25 hydroxy D2 and D3, by LC-MS/MS, serum microsample, quantitative
- 0039U TOS 5; Short Descriptor—Dna antb 2strand hi avidity; Long Descriptor—Deoxyribonucleic acid (DNA) antibody, double stranded, high avidity
- 0040U TOS 5; Short Descriptor—Bcr/abl1 gene major bp quan; Long Descriptor—BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative
- 0041U TOS 5; Short Descriptor—B brgdrferi antb 5 prtn igm; Long Descriptor—Borrelia burgdorferi, antibody detection of 5 recombinant protein groups, by immunoblot, IgM
- 0042U TOS 5; Short Descriptor—B brgdrferi antb 12 prtn igg; Long Descriptor—Borrelia burgdorferi, antibody detection of 12 recombinant protein groups, by immunoblot, IgG

- 0043U TOS 5; Short Descriptor—Tbrf b grp antb 4 prtn igm; Long Descriptor—Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgM
- 0044U TOS 5; Short Descriptor—Tbrf b grp antb 4 prtn igg; Long Descriptor—Tick-borne relapsing fever Borrelia group, antibody detection to 4 recombinant protein groups, by immunoblot, IgG0024U Glycosylated acute phase proteins (GlycA), nuclear magnetic resonance spectroscopy, quantitative
- 0012M TOS 5; Short Descriptor—Onc mrna 5 gen rsk urthl ca; Long Descriptor—Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and XCR2), utilizing urine, algorithm reported as a risk score for having urothelial carcinoma
- 0013M TOS 5; Short Descriptor—Onc mrna 5 gen recr urthl ca; Long Descriptor—Oncology (urothelial), mRNA, gene expression profiling by real-time quantitative PCR of five genes (MDK, HOXA13, CDC2 [CDK1], IGFBP5, and CXCR2), utilizing urine, algorithm reported as a risk score for having recurrent urothelial carcinoma

The following new code is effective January 1, 2018:

- 0011M TOS 5; Short Descriptor—Onc prst8 ca mrna 12 gen alg; Long Descriptor—Oncology, prostate cancer, mRNA expression assay of 12 genes (10 content and 2 housekeeping), RT-PCR test utilizing blood plasma and/or urine, algorithms to predict high-grade prostate cancer risk

#### Notes:

- In instances where Medicare-covered CLFS procedure codes do not yet appear on the quarterly CLFS file or the quarterly Integrated Outpatient Code Editor (I/OCE) update, MACs will locally price the codes until they appear on the CLFS file and/or, for Part A claims, the I/OCE.
- MACs will not search their files to either retract payment or retroactively pay claims; however, they should adjust claims that you bring to their attention.

## ADDITIONAL INFORMATION

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The official instruction, CR 10642, issued to your MAC regarding this change is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4045CP.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/>.

## DOCUMENT HISTORY

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Date of Change	Description
May 14, 2018	Initial article released.

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