



October 27, 2023

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-8016

RE: Preliminary Determinations for Calendar Year 2024 (CY2024) for New and Reconsidered Services on the Clinical Laboratory Fee Schedule (CLFS)

Dear Administrator Brooks-LaSure:

On behalf of the Association for Diagnostics & Laboratory Medicine (ADLM), thank you for the opportunity to submit comments on preliminary determinations on the Clinical Laboratory Fee Schedule (CLFS) for calendar year 2024 (CY2024) for new and reconsidered codes.

ADLM is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. ADLM brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

ADLM wishes to express its concerns regarding the preliminary decision by the Centers for Medicare and Medicaid Services (CMS) to crosswalk all new CPT codes 8X017; 8X018; 8X019; 8X020; 8X021; and 8X022 to CPT code 81445 (Targeted genomic sequence analysis panel, solid organ neoplasm, 5-50 genes). We believe that basing reimbursement for these services on gene numbers oversimplifies the comprehensive work laboratories must conduct to perform this testing.

- **CPT code 8X017** (Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, microsatellite instability)

ADLM recommends a crosswalk to CPT code 81455 minus 81277. This viewpoint is backed by stakeholders and unanimously supported by the Advisory Panel on Clinical Diagnostic Laboratory Tests, remains our recommendation. By excluding the copy number tasks from CPT code 81455, it better mirrors the diminished workload and resources required to perform the test.

- **CPT code 8X018** (Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, copy number variants, and microsatellite instability)

ADLM recommends aligning CPT code 8X018 with CPT code 81455, a position backed by stakeholders and unanimously supported by the Panel. Both CPT codes are genomic profiling tests, utilizing similar efforts and resources. Aligning CPT code 8X018 with 81455 offers a more accurate representation of the work and resources encompassed in 8X018.

- **CPT code 8X019** (Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements)

ADLM recommends aligning CPT code 8X019 with CPT code 0244U, a viewpoint backed by stakeholders and unanimously approved by the Panel. Both CPT codes, 8X019 and 0244U are genomic profiling tests sharing similar methods and resource use and evaluate tumor changes to determine optimal treatment. The intricate biomarker analysis of tumor mutational burden in CPT code 8X019 demands more extensive bioinformatics, development, and validation efforts, exceeding the scope of CPT code 81455.

- **CPT code 8X020** (Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (e.g., plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants and rearrangements)

ADLM recommends aligning CPT code 8X020 with CPT code 81455 with a 1.25 multiplier, a recommendation supported by stakeholders and unanimously approved by the Panel. CPT codes 8X020 and 81455 are genomic profiling tests with comparable methods and resource needs. Both focus on evaluating tumor changes to identify optimal treatments. A 1.25 multiplier accounts for the enhanced work and resources for sequencing circulating tumor DNA from plasma at 10,000X, compared to the typical 100-1000X for FFPE tumor DNA.

- **CPT code 8X021** (Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (e.g., plasma), interrogation for sequence variants; DNA analysis, copy number variants, and microsatellite instability)

ADLM recommends aligning CPT code 8X021 with CPT code 81455, coupled with a 1.25 multiplier. This recommendation is backed by stakeholders and unanimously supported by the Panel. Both CPT codes, 8X021 and 81455, are genomic profiling tests with similar methods and resource requirements. The alignment of CPT code 8X021 with 81455 provides an accurate portrayal of its efforts and the recommended 1.25 multiplier accounts for the added effort and resources for sequencing ctDNA from plasma at 10,000X, compared to the usual 100-1000X for FFPE tumor DNA.

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- **CPT code 8X022** (Solid organ neoplasm, genomic sequence analysis panel, cell-free nucleic acid (e.g., plasma), interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements)

ADLM recommends aligning CPT code 8X022 with CPT code 0244U incorporating a 1.25 multiplier. This perspective is backed by numerous stakeholders and endorsed by 7 out of 9 Panel members. Both CPT codes, 8X022 and 0244U, are genomic profiling tests with comparable methods and resource demands. The intricate biomarker analysis of tumor mutational burden in CPT code 8X022 demands more extensive bioinformatics and development efforts, exceeding the scope of CPT code 81455. The advised 1.25 multiplier accounts for the added labor and resources for sequencing ctDNA from plasma at 10,000X, compared to the typical 100-1000X for FFPE tumor DNA.

ADLM urges CMS to revise its preliminary determination to crosswalk CPT codes 8X017, 8X018, 8X019, 8X020, 8X021, and 8X022 to CPT code 81445. Adequate reimbursement is important to ensure continuing innovation and patient access for these laboratory procedures. Our recommendations are supported by the Panel, the stakeholder community, and we believe they are the most accurate representation of the work and resources encompassed for these tests.

Thank you for the opportunity to submit comments on the CY 2024 CLFS preliminary pricing determinations. We remain committed to working with you to ensure accurate pricing and secure patient access to laboratory tests. If you have any questions, please email Vince Stine, PhD, ADLM's Senior Director of Government and Global Affairs, at [vstine@myadlm.org](mailto:vstine@myadlm.org).

Sincerely,



Octavia M. Peck Palmer, PhD, FADLM  
President, ADLM