

October 27, 2023

VIA Electronic Mail to: [CLFS Annual Public Meeting@cms.hhs.gov](mailto:CLFS_Annual_Public_Meeting@cms.hhs.gov)

Sarah Shirey-Losso
Director, Division of Ambulatory Services
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CY 2024 CLFS Preliminary Determinations: 8X017-8X022

Dear Ms. Shirey-Losso:

On behalf of LUNGeVity Foundation, I am pleased to provide comments on the CY 2024 CLFS preliminary determinations for CPT codes 8X017 through 8X022. LUNGeVity Foundation is the nation's preeminent lung cancer nonprofit that funds research, provides education and support, and builds communities for the approximately 230,000 Americans diagnosed with lung cancer each year and the 538,243 Americans living with the disease¹. Our interest is in ensuring that lung cancer patients receive guideline-recommended multi-gene biomarker testing, typically performed with a next generation sequencing assay. Data show that patients who receive comprehensive multi-gene biomarker testing and are accurately treated based on the complete results of the test have better outcomes and live longer, higher-quality lives.²

Medical guidelines organizations such as the National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO) include the use of broad molecular panels prior to making treatment decisions for people with non-small cell lung cancer. Notably, these medical guidelines are the ones that providers and payers are most likely to rely on for care and coverage decisions. Multi-gene comprehensive biomarker testing is an essential part of any NSCLC patient's diagnosis due to the prevalence of more treatable biomarkers than any other cancer type. Having a streamlined system for coding the test used for the NSCLC patient's testing and ensuring that it is reimbursed at an appropriate level is critical for continuity of care for patients who rely on comprehensive biomarker testing for diagnosis of their specific sub-type of lung cancer.

When setting the initial payment rate for a clinical diagnostic laboratory test assigned a new code, CMS must crosswalk the test to "the most appropriate existing test" currently paid under the CLFS.³ Consistent with this requirement, 21 CFR 414.508(b)(1) states that "[c]rosswalking is used if it is determined that a new [test] is comparable to an existing test, multiple existing test codes, or a portion of an existing test code." CMS considers both "test methods and resources" when deciding whether a new test is "comparable" to an existing test.⁴

In the Preliminary Determinations, CMS proposes to crosswalk all six codes to 81445. In support of its proposed decision, CMS states:

¹ SEER. Cancer Stat Facts: Lung and Bronchus Cancer. 2019; <https://seer.cancer.gov/statfacts/html/lungb.html>. Accessed October 10, 2019.

² Aggarwal C, Marmarelis ME, Hwang WT, Scholes DG, McWilliams TL, Singh AP, Sun L, Kosteva J, Costello MR, Cohen RB, Langer CJ, Doucette A, Gabriel PN, Shulman LN, Rendle KA, Thompson JC, Bekelman JE, Carpenter EL. Association Between Availability of Molecular Genotyping Results and Overall Survival in Patients With Advanced Nonsquamous Non-Small-Cell Lung Cancer. *JCO Precis Oncol*. 2023 Jul;7:e2300191. doi: 10.1200/PO.23.00191. PMID: 37499192.

³ See Soc. Sec. Act § 1834A(c)(1).

⁴ 81 Fed. Reg. 41,036, 41,039 (June 23, 2016).

The descriptor for [code] does not specify what is being analyzed, therefore CMS does not see justification in crosswalking to a code that specifies analyzing more than 50 genes. CMS is instead proposing a crosswalk that analyzes 5-50 genes.

We agree that 8X017-8X022 do not specify the number of genes analyzed. However, the 5-50 gene panel described by 81445 is not “comparable” to the assays described by 8X017-8X022, as evidenced by the following:

- **Two codes (8X019, 8X022) include tumor mutation burden (TMB) analysis (among other markers).** Labs cannot produce reliable TMB results with a panel of 50 genes or less.⁵
- **Three codes (8X020-8X022) analyze cell-free DNA from blood specimens (as opposed to tumor tissue).** Tests described by new codes 8X020-8X022 detect tumor DNA/RNA present in the patient’s bloodstream. Detecting cell-free DNA requires substantially more resources than detection of DNA or RNA extracted directly from a tumor specimen (e.g., 81445).
- **Five codes (8X018-8X022) include copy number variant (CNV) analysis, among other markers (e.g., TMB, MSI). The proposed crosswalk would value the new codes at less than the current Medicare rate for stand-alone CNV analysis.** Stand-alone CNV analysis is reported with CPT code 81277. The CY 2023 CLFS rate for 81277 is \$1,160.00. The assays described by 8X018-8X022 report CNVs as well as certain additional variant types. Notwithstanding this additional work, CMS proposes a rate of ~\$597 for all 5 tests – i.e., a rate that is nearly 50% lower than the rate for CNV analysis alone.

As we noted earlier, access to multi-gene biomarker testing is critical for patients to receive the most personalized treatments that give them the best chance of positive outcomes. We are concerned that Medicare beneficiaries will lose access to the tests described by 8X017-8X022 unless Medicare establishes reimbursement rates that reflect the resources required to perform the tests. As such, we respectfully request that CMS use the stakeholder-recommended crosswalks for these codes:

- 8X017 Crosswalk to 81455 MINUS 81277
- 8X018 Crosswalk to 81455
- 8X019 Crosswalk to 0244U
- 8X020 Crosswalk to 81455 TIMES 1.25
- 8X021 Crosswalk to 81455 TIMES 1.25
- 8X022 Crosswalk to 0244U TIMES 1.25

If CMS does not agree that these recommended crosswalks are “comparable” to their respective codes, we urge CMS to allow the local Medicare Administrative Contractors (MACs) to price these codes (via the “gapfill” process) instead of finalizing crosswalk to 81445.

* * * *

We appreciate your attention to this request. If you have any questions, please contact me at bleonard@lungevity.org.

⁵ See Vega DM, et al. Aligning tumor mutational burden (TMB) quantification across diagnostic platforms: phase II of the Friends of Cancer Research TMB Harmonization Project. *Ann Oncol* 2021;32(12):1626-1636 – see Table 1. <https://doi.org/10.1016/j.annonc.2021.09.016>.

October 27, 2023
Page 3 of 3

Sincerely,

A handwritten signature in black ink that reads "Brandon Leonard". The signature is written in a cursive, flowing style.

Brandon Leonard
Senior Director, Government Affairs
LUNGeivity Foundation