PERSONALIZED MEDICINE COALITION

October 26, 2023

Ryan Howe, PhD
Acting Director, Division of Ambulatory Services
Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: 2024 *Clinical Lab Fee Schedule* Preliminary Determinations for genomic sequencing procedures

Dear Dr. Howe:

On behalf of the Personalized Medicine Coalition (PMC), which is comprised of more than 200 scientific, industry, patient, provider, and payer institutions, I am writing in response to the CY 2024 *Clinical Laboratory Fee Schedule* (CLFS) Preliminary Determinations for genomic sequencing procedures proposed by the Centers for Medicare & Medicaid Services (CMS).[i] PMC is concerned that the CLFS rates for genomic sequencing procedures 8X017-8X022 in the CY 2024 Preliminary Determinations do not adequately reflect the significant cost and resources required to perform complex and specialized testing. As explained below, PMC opposes the proposed reduced rates because they will likely lead to fewer genomic testing options for physicians and, by extension, decrease patient access to targeted therapies identified for use based on results from genomic sequencing procedures. We strongly urge CMS to assign rates for genomic sequencing procedures in the Final Determination that better reflect the resources required to develop and furnish genomic profiling tests.

PMC defines personalized medicine as an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients.

Personalized medicine is helping to shift the patient and provider experiences away from trial-and-error treatments of late-stage diseases toward more streamlined approaches to disease prevention and treatment, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC and its members are leading the way in personalized medicine and in developing evidence showing how patients and the health care system can benefit from appropriate testing and tailored treatment as soon as possible during their clinical experiences.

Statement of Neutrality

PMC's members may present their own responses to the CY 2024 CLFS Preliminary Determinations and actively advocate for those positions. PMC's response is designed to provide feedback so that the general concept of personalized medicine can advance, and is not intended to impact adversely the ability of individual PMC members, alone or in combination, to submit separate responses to CMS on the CLFS CY 2024 Preliminary Determinations.

Proposed CLFS Rates May Limit Personalized Medicine in Oncology

Several types of genomic profiling tests are included in clinical guidelines to examine broad panels of genes and detect the main classes of genomic alterations driving cancer growth as well as their genomic signatures. Patients living with cancer rely on results from genomic sequencing procedures utilized by their physicians to identify mutations that allow them to select therapies targeting a patient's specific cancer. The National Comprehensive Cancer Network (NCCN) regularly publishes guidelines reflecting the importance of these tests for patient care.[ii]

Just a decade ago, personalized medicines accounted for less than 10 percent of the new therapies approved by the U.S. Food and Drug Administration each year. In contrast, PMC's annual analyses have shown that for each of the last eight years, personalized medicines accounted for at least a quarter of new drug approvals. More than half of these have been targeted cancer therapies.[iii] However, personalized medicine approaches still face clinical implementation challenges, some directly linked to payment for diagnostic testing. A 2021 PMC study examining care for patients with non-small-cell lung cancer cited limited coverage and reimbursement for diagnostics as a factor driving underutilization of tests to identify actionable mutations.[iv]

Due in part to the growing number of targeted therapies to treat common, complex, and rare cancers, more patients can and should benefit from genomic sequencing procedures. Unfortunately, CMS' proposal to set CY 2024 CLFS rates for genomic sequencing procedures 8X017-8X022 nearly 80 percent lower than rates recommended by laboratory stakeholders and the Clinical Diagnostic Laboratory Test (CDLT) Advisory Panel could roll back recent improvements in patient care made possible by personalized medicine. With payments set at markedly lower levels, disruptions caused by laboratories' inability to offer genomic sequencing procedures will endanger patient and physician access to genomic profiling tests. Furthermore, without appropriate and timely reimbursement, diagnostic developers will be unable to innovate at the pace required to push the field of personalized medicine forward.

Conclusion

Pricing genomic sequencing procedures fairly will enable personalized medicine to continue supporting what is rapidly becoming the standard of care in many areas of oncology. In the Final Determination for CY 2024, PMC urges CMS to properly set CLFS payment rates for the genomic sequencing procedure codes 8X017-8X022 to adequately capture the nature and costs of performing these potentially life-saving tests. If you have any questions about these comments, please contact me at 202-499-0986 or by email at cbens@personalizedmedicinecoalition.org.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy

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[i] Centers for Medicare and Medicaid Services. 2024 *Clinical Lab Fee Schedule* Preliminary Determinations https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule-clfs/annual-public-meetings.(Accessed October 26, 2023)

[ii] National Comprehensive Cancer Network. Treatment Guidelines by Cancer Type. https://www.nccn.org/guidelines/category_1. (Accessed October 25, 2023)

[ii] Personalized Medicine Coalition. *Personalized Medicine at FDA: The Scope & Significance of Progress in 2022*. February 22, 2023. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/report.pdf. (accessed October 25, 2023).

[ii] Pritchard, D., Hulick, P.J., Wells, C.J. "The Integration of Personalized Medicine into health systems: progress and a path forward". *Future Medicine*. October 21, 2021. https://www.futuremedicine.com/doi/full/10.2217/pme-2021-0102. (Accessed October 25, 2023)