ASSOCIATION FOR MOLECULAR PATHOLOGY
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October 24th, 2022

Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1770-P
P.O. Box 8016,
Baltimore, MD 21244-8016

RE: Preliminary Determinations for Calendar Year 2023 (CY2023) for New and Reconsidered Services on the Clinical Laboratory Fee Schedule (CLFS)

Dear Brooks-LaSure:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit comments on preliminary determinations on the Clinical Laboratory Fee Schedule (CLFS) for calendar year 2023 (CY2023) for new and reconsidered codes. In this comment letter, we have outlined our concerns about the pricing for the Oncomine Dx Target Test (PLA code 0022U).

AMP is an international medical and professional association representing approximately 2,600 physicians, doctoral scientists, and medical laboratory scientists (technologists) who perform laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Our membership includes professionals from the government, academic medicine, clinical testing laboratories, and the in vitro diagnostics (IVD) industry.
AMP previously commented on PLA code 0022U in response to the preliminary determinations of the CY 2019 Clinical Laboratory Fee Schedule. At that time AMP's concern was regarding the crosswalk to 81445. In the CY2019 final determinations, 0022U was assigned to be gapfilled, consistent with AMP's comments. Since the original gapfilling process the PLA code 0022U has been priced at $1,950 for four years. Therefore, AMP is disappointed to see that the revised 0022U was proposed to be crosswalked to CPT Code 81445 (at $597) in the CY Preliminary Determinations. This pricing would be detrimental to laboratories as the cost of running the test is much more than the reimbursement specified in the Preliminary Determination. For example, the test kit for this test (not including the upfront costs of instrumentation, training, and validation) is priced at $750, with total cost to run this test ranging from $1,400-$1,900 per sample. With the preliminary determination of crosswalking 0022U to CPT code 81445, clinical laboratories would only be reimbursed for one third, or less, of the cost of running the test, potentially forcing providers to no longer offer 0022U and negatively affecting patient access.

This test is a qualitative in vitro diagnostic test that uses targeted high-throughput, parallel-sequencing technology to detect sequence variations in 23 genes in DNA and RNA isolated from formalin-fixed, paraffin-embedded tumor (FFPE) tissue samples from patients with non-small cell lung cancer (NSCLC) using the Ion PGM Dx System. This IVD test is used by a number of AMP member laboratories to provide testing to Medicare patients. A likely consequence of and only other option for laboratories in place of PLA Code 0022U would be to use the less efficient method of testing for crucial biomarkers in NSCLC patient samples; laboratories would be forced to offer individual biomarker testing of each analyte, which has been shown to reduce the number of

biomarkers than can successfully be performed, and will ultimately result in suboptimal care for Medicare cancer patients as well as increased costs to the Medicare system.

AMP urges CMS not to finalize this preliminary determination as it would have a significant and negative impact on patient access and AMP member laboratories. In 2019, AMP compared several factors to determine the most appropriate recommendation. However, there was no existing code on the CLFS that compared to PLA Code 0022U, leading AMP to recommend gapfill. As PLA Code 0022U is a revision of an existing CLFS code, **AMP recommends that CMS crosswalk the revised 0022U to the current 0022U and maintain the original gapfill rate, as supported by multiple stakeholders and voted for by 12 out of 12 of the Advisory Panel on Clinical Diagnostic Laboratory Tests**.

We thank you for the opportunity to submit these comments on the CY 2023 CLFS preliminary pricing determinations. We believe that the information provided above will result in more accurate pricing for PLA Code 0022U. We are happy to answer any questions about our recommendations and provide follow up information. Please direct your correspondence to Sarah Thibault-Sennett, Director of Public Policy and Advocacy, at sthibaultsennett@amp.org.

Sincerely,

Jay Patel, MD
AMP Economic Affairs Committee Vice Chair: New Codes and Pricing