January 31, 2020

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

American
Clinical Laboratory
Association

Submitted via email: CLFS_Annual_Public_Meeting@cms.hhs.gov

Dear Ms. Shirey-Losso,

The American Clinical Laboratory Association (ACLA) is pleased to submit our reconsideration request on the Calendar Year (CY) 2020 Clinical Laboratory Fee Schedule (CLFS) Final Payment Determinations ("Final Determinations")[1], which include a small number of modifications from our oral comments during the CLFS Annual Public Meeting on June 24, 2019 and written comments on the CY 2020 CLFS Preliminary Determinations.

ACLA is a non-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, and end-stage renal disease, hospital, and nursing home laboratories. ACLA members are actively engaged in the development and performance of the tests billed to the Medicare program under the CLFS. We have a vested interest in ensuring that the diagnostic testing services represented by the new and reconsidered codes are reimbursed appropriately and adequately to ensure access to the tests by Medicare beneficiaries.

ACLA is submitting a reconsideration request of the crosswalk for the new PALB2 molecular pathology Tier 1 code 81307 (PALB2 full gene sequence).[2] In addition to this request, we will provide stakeholder input at the upcoming 2020 CLFS Annual Public Meeting. We urge CMS to take these comments into account when reviewing our reconsideration request.

ACLA is concerned about CMS's approach to crosswalking the new PALB2 full gene sequence molecular pathology Tier 1 code 81307.

CMS based its final determination for the new Tier 1 PALB2 full gene sequence code (81307) on a crosswalk to the Tier 2, Level 7 code 81406, with a National Limitation Amount (NLA) of $282.88. Payment for Tier 2 codes was based on a median price for all of the various genes for each Tier 2 Level 1-9 codes, and Tier 2 codes increase in complexity with each level, which should result in an increased NLA. However the Tier 2, Level 7 code to which the agency crosswalked CPT code 81307 appears to be an anomaly, since the NLA ($282.88) is lower than that for the Tier 2, Level 6 code 81405 ($301.35). This reimbursement anomaly for the Tier 2, Level 7 code (81406) does not reflect the additional work and resources required for tests included in that code, and crosswalking the PALB2 full gene sequencing code 81307 to the outlier Tier 2, Level 7 code 81406 would not account

[1] https://www.cms.gov/files/zip/cy-2020-clinical-laboratory-fee-schedule-test-codes-final-determinations

[2] The full code descriptor is "PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; full gene sequence".

for the increased complexity required for a full gene sequence. We urge CMS to bear such differences in mind when determining how best to set reimbursement levels for this new code.

ACLA recommends that CMS instead crosswalk CPT code 81307 to 81317 (PMS2, postmeiotic segregation increased 2 [S. cerevisiae]) (eg, hereditary non-polyposis colorectal cancer, Lynch syndrome) gene analysis; full sequence analysis. PALB2 has 14 exons, 1186 amino acids; PMS2 has 14 exons, 863 amino acids. This analyte-specific crosswalk represents similar work and resources. The Tier 1 CPT code 81317 is a more appropriate crosswalk for code 81307, as the work and resources align with the number of exons studied in the PALB2 gene analysis, full gene sequence.

Following the CY 2020 Clinical Diagnostic Laboratory Test Panel Meeting in July 2019, the Medicare Advisory Panel on Clinical Diagnostic Tests ("The Advisory Panel") voted unanimously in favor of our recommendations for crosswalking the PALB2 full gene sequence code. CMS's CY 2020 final determinations do not follow the recommendations of the agency's own Advisory Panel on CDLTs. The Protecting Access to Medicare Act of 2014 (PAMA) established the Medicare Advisory Panel on Clinical Laboratory Diagnostic Tests at Section 216(f)) (1) for "the establishment of payment rates under this section for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test." We disagree with CMS's decision to dismiss the Advisory Panel's recommendation on this code.

Although we recognize that the decision on payment methodologies lies with CMS, surely Congress did not intend for the Advisory Panel to be largely ignored by the Agency in setting its preliminary payment determinations. This is especially true when the Advisory Panel's recommendations were most often supported by stakeholder comments.

Further, in the case of the PALB2 full gene sequence code, CMS's crosswalks were not proposed by any stakeholders or any of the expert Advisory Panel members. In the past when CMS has rejected recommendations from the Advisory Panel, it typically has done so in favor of a stakeholder recommendation, or vice versa. In this case, stakeholders and the Advisory Panel made other recommendations for crosswalking to a code whose work and resources better approximate the work and resources for a PALB2 full gene sequence.

* * * *

Thank you very much for your consideration of ACLA's reconsideration request on the new PALB2 full gene sequence code. Please do not hesitate to contact us if you have questions or need additional information.

Sincerely,

Joan Kegerize, J.D.
Vice President, Reimbursement & Scientific Affairs