AMERICAN CLINICAL LABORATORY ASSOCIATION

January 20, 2021

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

Submitted via email: CLFS_Annual_Public_Meeting@cms.hhs.gov

RE: ACLA Reconsideration Request on the 2021 Clinical Laboratory Fee Schedule Final Payment Determinations

Dear Ms. Shirey-Losso,

The American Clinical Laboratory Association (ACLA) is pleased to submit our reconsideration request on the Calendar Year (CY) 2021 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 22, 2020 and written comments on the CY 2021 CLFS Preliminary Determinations.

The American Clinical Laboratory Association (ACLA) is the national trade association representing leading laboratories that deliver essential diagnostic health information to patients and providers. ACLA members are at the forefront of driving diagnostic innovation to meet the country's evolving health care needs and provide vital clinical laboratory tests that identify and prevent infectious, acute, and chronic disease. The association's members also have been a critical component of the response to the COVID-19 pandemic, having performed over 93 million COVID-19 diagnostic and serologic tests to date.

ACLA is submitting a reconsideration request of the crosswalk for the new therapeutic drug codes 80151 (Amiodarone), 80161 (Carbamazepine; 10,11-epoxide), 80167 (Felbamate), and 80181 (Flecainide) and new Tier 1 molecular pathology codes 81279 (JAK 2 kinase, target sequence analysis)[2], and 81338 (MPL, gene analysis; common variants)[3]. In addition to this request, we will provide stakeholder input at the upcoming 2021 CLFS Annual Public Meeting. We urge CMS to take these comments into account when reviewing our reconsideration request. While CMS asked stakeholders to comment on each specific code, we have serious concerns about CMS's approach to decisions that do not follow the majority recommendations of the Agency's own Medicare Advisory Panel on Clinical Laboratory Diagnostic Tests (CDLT Panel).

Therapeutic Drug Test Codes

ACLA is concerned about CMS's approach to crosswalking the new therapeutic drug test codes. The agency decided to crosswalk the new test codes 80151 (Amiodarone), 80161 (Carbamazepine; 10,11-epoxide), 80167

[1] https://www.cms.gov/files/zip/cy-2021-clinical-laboratory-fee-schedule-test-codes-final-payment-determinations-ver-1.zip.
[2] The full descriptor is "JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13)."
[3] The full descriptor is "MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; common variants (eg, W515A, W515K, W515L, W515R)."

(Felbamate), and 80181 (Flecainide) to a generic method code 80299, *Quantitation of therapeutic drug, not elsewhere specified.* The crosswalk to 80299 pricing does not reflect the technical nuances of the different therapeutic drugs.

We recommend CMS reconsider its Final Determinations and crosswalk the new drug codes 80151 (Amiodarone), 80161 (Carbamazepine; 10,11-epoxide), and 80181 (Flecainide) to an analyte specific therapeutic drug code 80155 (Caffeine). The new codes are performed by LC-MS/MS methodology and have similar work and resources as 80155. The crosswalk to Caffeine code 80155 more accurately represents the methodology, work and resources for testing of these new therapeutic drug codes. This crosswalk aligns with the method CMS and the Panel used to crosswalk the drug codes for the 2019 CLFS.

ACLA recommends a crosswalk for the new therapeutic drug code 80167 (Felbamate) to code 80199 (Tiagabine). This code represents similar methodology and resources to perform the testing and is also used to treat seizures/epilepsy. We do not agree with a crosswalk to the unspecified therapeutic drug code 80299, especially in light of the fact that code 80199 is a quantitative assay for an epileptic drug used to treat epilepsy and seizures. The CDLT Panel vote was a tie for 80199 and 80299 and we urge CMS to adopt the analyte specific approach for a crosswalk to Tiagabine code 80199. This crosswalk aligns with the method CMS and the Panel used to crosswalk the drug codes for the 2019 CLFS.

Molecular Pathology Tier 1 Codes

ACLA is concerned about CMS's approach to crosswalking the new Tier 1 molecular pathology codes 81279 (JAK 2 kinase, target sequence analysis), and 81338 (MPL, gene analysis; common variants) to a Tier 2 Level code.

<u>81279 (JAK2)</u>

ACLA recommends CMS reconsider its Preliminary Determinations and crosswalk 81279 to an analyte specific code 81272, *KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, gastrointestinal stromal tumor [GIST], acute myeloid leukemia, melanoma), gene analysis, targeted sequence analysis (eg, exons 8, 11, 13, 17, 18).* The JAK2 targeted sequence analysis methodology, resources, and amount of genetic material sequenced are comparable to that of KIT targeted sequence analysis.

We believe using the Tier 1 CPT 81272 is a more appropriate crosswalk for code 81279 as the work and resources align with exons studied in the JAK2 targeted gene sequence analysis. We do not agree with the CMS rationale that the crosswalk approach to a Tier 2 code is more transparent than an analyte specific Tier 1 code. ACLA takes issue with this crosswalk approach. A more transparent method is to crosswalk a new Tier 1 code to an analyte specific Tier 1 code and we urge CMS to reconsider its approach and crosswalk the JAK2 code 81279 to the KIT code 81272.

<u>81338 (MPL)</u>

ACLA recommends CMS reconsider its Final Determinations and crosswalk 81338 to an analyte specific code 81120, *IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants (eg, R132H, R132C).* The methodology, resources, and amount of genetic material sequenced are comparable to that of IDH1 common variants. Both assess genes for an oncology disorder and both are 1 exon targeted sequencing for oncology samples.

We believe using the Tier 1 CPT 81120 is a more appropriate crosswalk for code 81338 as the IDH1 work and resources align with exons studied in the MPL gene analysis for common variants. We do not agree with the CMS rationale that the crosswalk approach to a Tier 2 code is more transparent than an analyte specific Tier 1 code. ACLA takes issue with this crosswalk approach. A more transparent method is to crosswalk a new Tier 1 code to an analyte specific Tier 1 code and we urge CMS to reconsider its approach and crosswalk the MPL code 81338 to the IDH1 code 81120.

Following the CY 2021 Clinical Diagnostic Laboratory Test Panel Meeting in July 2020, the CDLT Panel voted unanimously in favor of our recommendations for crosswalking the JAK2 targeted gene sequence analysis and MPL gene analysis codes. CMS's CY 2021 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 JAK2 targeted gene analysis and MPL gene analysis codes, CMS's crosswalks were not proposed by any stakeholders or any of the expert CDLT Panel members. In the past when CMS has rejected recommendations from the CDLT Panel, it typically has done so in favor of a stakeholder recommendation, or vice versa. In this case, stakeholders and the CDLT Panel made other recommendations for crosswalking to a code whose work and resources better approximate the work and resources for a JAK2 targeted gene sequence analysis and MPL gene analysis codes.

The CDLT Panel was one hundred percent (100%) aligned with our recommendations as well as other laboratory stakeholder comments. While CMS asked stakeholders to comment on each specific code, we have serious concerns about CMS's approach to ignore the recommendations of the Agency's own CDLT Panel.

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Thank you very much for your consideration of ACLA's reconsideration request on the new therapeutic drug and molecular pathology codes. If there are any questions regarding these comments, please do not hesitate to contact us by phone (202)-637-9466 or via email at jkegerize@acla.com.

Sincerely,

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