ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
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January 20, 2021

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

Submitted via email: CLFS_Annual_Public_Meeting@cms.hhs.gov

Dear Ms. Shirey-Losso:

In November, the Centers for Medicare & Medicaid Services (CMS) issued the final payment determinations for new codes on the CY 2021 Clinical Laboratory Fee Schedule (CLFS). Prior to their release, the Association for Molecular Pathology (AMP) submitted payment recommendations for these codes at the public meeting held last June, and we appreciate that CMS finalized many payment determinations consistent with the proposed crosswalks recommended by AMP and the Clinical Diagnostic Laboratory Tests (CDLT) Advisory Panel. However, following careful review of the final determinations, AMP respectfully requests reconsideration of CPT codes 81338 and 81279 on the basis of the final payment amounts.

AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from the government, academic medicine and the in vitro diagnostics industry. AMP members are experts in molecular pathology, and the implementation of and coverage and payment determinations for these codes have a direct impact on their practice.

AMP recognizes that in recent years, CMS has regularly crosswalked services to Tier 2 molecular pathology codes for new Tier 1 molecular tests. CMS believes this approach to be a more "transparent and consistent method;" however, we respectfully disagree with this approach, and continue to believe a crosswalk to the Tier 2 codes, as proposed by CMS, does not always adequately address the amount of work involved and resources required to perform the testing for these services. Each Tier 2 code houses numerous codes that are grouped based on gene size. However, this general grouping with one price for each Tier 2 code often does not elicit the best crosswalk recommendation for many codes, even if the test described by the new code was once housed under that Tier 2 code. The reason for this is that now there are numerous Tier 1 molecular pathology codes established on the CLFS, which provides CMS with more specific options to more accurately crosswalk codes. AMP continues to believe that crosswalking new Tier 1 codes to the most specific existing Tier 1 option, when available, is the best approach to more closely match methodology, resources, and amount of genetic material interrogated.

AMP is committed to ensuring that molecular testing is properly valued to protect patient access to medically necessary testing. For these reasons, AMP requests that CMS reconsider its final payment determination for CPT codes 81338, 81339, and 81279.

81338 – MPL, gene analysis; common variants

- **CDLT Advisory Panel Outcome:** Unanimous support for crosswalk to Tier 1 Molecular Pathology Procedure 81120 (*IDH1*, common variants)
- **AMP Recommendation:** Crosswalk to 81120 (Payment=$193.25)
- **CMS Final Determination:** Crosswalk to 81402 (Payment=$150.33)
- **CMS Rationale:** *"Finalize as proposed. CMS continues to disagree with the recommendation of the CDLT Panel and commenters to crosswalk molecular pathology tests to different gene analysis tests. In the most recent years, CMS utilized codes known as "Tier 2 molecular pathology" test codes as crosswalks for these types of tests. Tier 2 molecular pathology test codes are based on ranges of genetic analysis (i.e. 2-5 exons, 3-5 genes). We finalized this crosswalking approach for the past two years as we believe it to be a more transparent and consistent method."*

At the outset, AMP along with other stakeholders and the Advisory Panel recommended a crosswalk to CPT code 81120 (*IDH1*, common variants). AMP believes the methodology, resources, and amount of genetic material sequenced are comparable to that of *IDH1* common variants as both are testing of variants in one codon in genes for oncology disorders. CPT code 81338 closely matches an existing test, and **for these reasons, AMP recommends that CMS reconsider its payment determination for CPT code 81338, and adopt the crosswalk recommendation of CPT code 81120.**

81339 – MPL, gene analysis; sequence analysis, exon 10

- **CDLT Advisory Panel Outcome:** Unanimous support for crosswalk to Tier 1 Molecular Pathology Procedure 81310 (*NPM1*, gene analysis, exon 12 variants)
- **AMP Recommendation:** Crosswalk to 81310 (Payment=$246.52)
- **CMS Final Determination:** Crosswalk to 81403 (Payment=$185.20)
- **CMS Rationale:** "*Finalize as proposed. CMS continues to disagree with the recommendation of the CDLT Panel and commenters to crosswalk molecular pathology tests to different gene analysis tests. In the most recent years, CMS utilized codes known as "Tier 2 molecular pathology" test codes as crosswalks for these types of tests. Tier 2 molecular pathology test codes are based on ranges of genetic analysis (i.e. 2-5 exons, 3-5 genes). We finalized this crosswalking approach for the past two years as we believe it to be a more transparent and consistent method."*

AMP continues to recommend a crosswalk to CPT code 81310 (*NPM1*, gene analysis, exon 12 variants) for CPT code 81339. This recommendation remains consistent with the majority Panel recommendation and recommendations from other stakeholders. The methodology, resources, and amount of genetic material sequenced are comparable as both are 1 exon targeted sequencing for oncology samples. **Due to the similarity between these services, AMP recommends that CMS reconsider its payment determination for CPT code 81339, and adopt the crosswalk recommendation of CPT code 81310.**

81279 – JAK2, targeted sequence analysis

- **CDLT Advisory Panel Outcome:** Unanimous support for crosswalk to Tier 1 Molecular Pathology Procedure 81272 (*KIT*, gene analysis, targeted sequence analysis)
- **AMP Recommendation:** Crosswalk to 81272 (Payment=$329.51)
- **CMS Final Determination:** Crosswalk to 81403 (Payment=$185.20)
- **CMS Rationale:** *"Finalize as proposed. CMS continues to disagree with the recommendation of the CDLT Panel and commenters to crosswalk molecular pathology tests to different gene analysis tests. In the most recent years, CMS utilized codes known as "Tier 2 molecular pathology" test codes as crosswalks for these types of tests. Tier 2 molecular pathology test codes are based on ranges of genetic analysis (i.e. 2-5 exons, 3-5 genes). We finalized this crosswalking approach for the past two years as we believe it to be a more transparent and consistent method."*

For CPT code 81279, AMP continues to recommend a crosswalk to CPT code 81272 (KIT, gene analysis, targeted sequence analysis). This was our original recommendation and is consistent with the recommendation of other stakeholders as well as the Advisory Panel. We believe the methodology, resources, and amount of genetic material sequenced are comparable to that of *KIT* targeted sequence analysis. Because a similar service already exists, **AMP recommends that CMS reconsider its payment determination for CPT code 81279, and adopt the crosswalk recommendation of CPT code 81272.**

Thank you for your consideration of this request. We believe that the rationale, data, and recommendations provided above will result in more accurate pricing for these laboratory tests. Additional stakeholder input at the upcoming 2021 CLFS public meeting will provide clarification regarding the typical resources required to perform these services, the clinical uses for these services, as well as the manner in which these services compare and/or contrast to the typical technology existing services paid on the clinical laboratory fee schedule Please direct your correspondence to Tara Burke, Senior Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Antonia R. Sepulveda, MD, PhD
President, Association for Molecular Pathology