



ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care

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October 21, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

SUBMITTED ELECTRONICALLY VIA [CLFS Annual Public Meeting@cms.hhs.gov](mailto:CLFS_Annual_Public_Meeting@cms.hhs.gov)

RE: Preliminary Determinations for Calendar Year (CY) 2021 for New and Reconsidered Services on the Clinical Laboratory Fee Schedule (CLFS)

Dear Administrator Verma:

The Association for Molecular Pathology (AMP) appreciates the opportunity to provide comments on the preliminary determinations for calendar year (CY) 2021 for new and reconsidered services on the Clinical Laboratory Fee Schedule (CLFS). AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Our membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry. AMP members are experts in molecular pathology, and the implementation of and coverage and payment determinations for the codes on the CLFS have a direct impact on their practice. We firmly share CMS' goal to appropriately price each code on the CLFS and protect Medicare beneficiary access to testing.

CY 2021 CLFS Preliminary Determinations for Reconsidered and New Codes

AMP presented recommendations at the CLFS Annual Public Meeting on June 26, 2020, and we appreciate the agency provided many preliminary determinations consistent with our recommendations, particularly the preliminary recommendation for reconsidered code 81307, which AMP has provided comments on previously. In this letter, we also write to address concerns about some preliminary determinations, which we fear may lead to suboptimal prices that do not adequately account for the work and resources required to perform each test, and if prices are not adjusted may limit beneficiary access to these necessary services.

81307 - PALB2 (partner and localizer of BRCA2) (eg, breast and pancreatic cancer) gene analysis; full gene sequence

The preliminary determination proposed by CMS is a crosswalk to CPT code 81317 (PMS2, gene analysis; full sequence analysis). AMP strongly supports CMS' rationale for pricing 81307 which aligns with the recommendations of AMP, other stakeholders, and the majority CDLT Panel to crosswalk 81307 to 81317. As we have previously commented, a crosswalk to 81317 is the most accurate crosswalk as it accounts for not only the methods and resources required, but also the amount of genetic material interrogated. We appreciate CMS' reassessment of its recommendation for this code and support this preliminary determination made by CMS.

87635 - Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique

At the meeting of the Advisory Panel for Clinical Diagnostic Laboratory Test on July 29, 2020, the Panel supported a crosswalk to 87501 (*Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, includes reverse transcription, when performed, and amplified probe technique, each type or subtype*) with 9 votes; there were 2 votes for gapfill and 1 abstention. A member of the panel suggested that code 87501 was a more appropriate crosswalk for the reason that SARS-CoV-2 testing is seeking to detect a single virus, like tests under 87501 seek to detect a single type of influenza. In the preliminary determinations, CMS ultimately recommended gapfill for new code 87635. The agency's rationale is as follows:

“CMS agrees with the majority recommendation of the CDLT Panel to gapfill this code so that the resources used in this code can be better estimated by a Medicare Administrative Contractor (MAC).”

We respectfully disagree with CMS' proposal to send this new code to gapfill. AMP along with other stakeholders involved in testing for SARS-CoV-2 are united in supporting a recommendation to crosswalk 87635 to 87502 (*Infectious agent detection by nucleic acid (DNA or RNA); influenza virus, for multiple types or subtypes, includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, first 2 types or subtypes*). In a letter dated September 7, 2020, AMP and others outlined the additional costs involved in the development of these tests and the ongoing operational costs for facilitating these tests. The information outlined in this stakeholder letter, as well as the information presented by stakeholders including AMP at the Advisory Panel Meeting, provides CMS with the necessary information required to make an accurate pricing recommendation, rather than sending this code to gapfill.

Demand for SARS-CoV-2 testing continues to increase in response to the COVID-19 pandemic. Test developers have invested significant resources and delayed other projects to assist in the development of a SARS-CoV-2 amplified probe test in response to the pandemic. As we have mentioned, laboratories performing these lifesaving tests continue to incur significant costs. For example, some laboratories have struggled to implement platforms, expand staffing and have experienced higher labor costs. For these reasons, we strongly urge CMS to establish fair and appropriate reimbursement for 87635 by crosswalking to 87502. This recommendation, which is supported by AMP and aligned with the broader stakeholder community is consistent with the resources and work required to develop and furnish these tests.

New Molecular Pathology Codes 8X006-8X008

1. 8X006 – MPL, gene analysis; common variants

The CDLT Advisory Panel unanimously supported a crosswalk to Tier 1 Molecular Pathology Procedure 81120 (IDH1, common variants) by 12 votes, yet CMS proposed a crosswalk to Tier 2 Molecular

Pathology Procedure 81402 (Level 3) in the preliminary determinations. AMP continues to recommend a crosswalk to 81120, consistent with the majority Panel recommendation. The methodology, resources, and amount of genetic material sequenced are comparable as both are testing of variants in one codon in oncology samples.

2. 8X007 – MPL, gene analysis; sequence analysis, exon 10

The CDLT Advisory Panel unanimously supported a crosswalk to Tier 1 Molecular Pathology Procedure 81310 (NPM1, gene analysis, exon 12 variants) by 12 votes, yet CMS proposed a crosswalk to Tier 2 Molecular Pathology Procedure 81403 (Level 4) in the preliminary determinations. AMP continues to recommend a crosswalk to 81310, consistent with the majority Panel recommendation. The methodology, resources, and amount of genetic material sequenced are comparable as both are 1 exon targeted sequencing for oncology samples.

3. 8X008 – JAK2, targeted sequence analysis

The CDLT Advisory Panel unanimously supported a crosswalk to Tier 1 Molecular Pathology Procedure 81272 (KIT, gene analysis, targeted sequence analysis) by 12 votes, yet CMS proposed a crosswalk to Tier 2 Molecular Pathology Procedure 81403 (Level 4) in the preliminary determinations. AMP continues to recommend a crosswalk to 81272, consistent with the majority Panel recommendation. The methodology, resources, and amount of genetic material sequenced are comparable.

For new codes 8X006-8X008, CMS provided the following rationale for its proposed crosswalks:

“CMS disagrees 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 would like to request that CMS reconsider its preliminary determinations and blanket use of the Tier 2 codes as crosswalks. We continue to recommend that CMS adopt the crosswalk recommendations provided by AMP, other stakeholders, and all of the experts on the Advisory Panel.

For these codes, a crosswalk to the Tier 2 codes proposed by CMS does not adequately address the amount of work involved and resources required to perform the testing.

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 new code was once housed under that Tier 2 code. The reason for that is now that there are numerous Tier 1 molecular pathology codes established on the CLFS, which provides CMS and stakeholders with many other more specific options to more accurately crosswalk a code. AMP remains concerned that CMS has continued to utilize codes known as Tier 2 molecular pathology test codes as crosswalks for these types of tests. After a thorough analysis, AMP believes that the above-mentioned Tier 1 codes would be more appropriate and accurate crosswalks for 8X006-8X008, rather than the Tier 2 codes recommended by CMS.

Thank you for the opportunity to provide comments on the CY 2021 CLFS preliminary pricing determinations. We are committed to working with you to ensure accurate pricing and secure patient access to laboratory tests. Should you have any questions or require additional information, please direct your correspondence to Tara Burke, Senior Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Karen E. Weck, MD FCAP
President, Association for Molecular Pathology