



November 7, 2014

VIA electronic mail to Glenn.McGuirk@cms.hhs.gov

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: New Clinical Diagnostic Laboratory Test Codes for the Clinical Laboratory Fee Schedule for Calendar Year 2015.

Dear Administrator Tavenner:

On behalf of the Coalition for 21st Century Medicine, I am writing to thank you for the recently released CY2015 Clinical Laboratory Fee Schedule (CLFS) Preliminary Payment Determinations. We agree with CMS' decision to gapfill the payment rates for the new Multianalyte Assays with Algorithmic Analyses (MAAAs), Genomic Sequencing Procedures (GSPs) and other Molecular Multianalyte Assays codes.

The Coalition comprises many of the world's most innovative diagnostic technology companies, clinical laboratories, physicians, venture capital companies, and patient advocacy groups. Given the Coalition's mission to facilitate development and commercialization of innovative diagnostics to inform important patient management decisions, we have a keen interest in the agency's CLFS payment policies and determinations—especially those addressing coding and payment for these new and highly advanced testing procedures.

Coalition member labs have developed diagnostics that make personalized medicine possible. By understanding the molecular nature of disease, these new tests allow clinicians and patients to select individualized treatment options, rather than basing treatment choices on broad assessment of what works best for a population. Member tests, among other things, assess cancer risk, identify productive chemotherapies, and predict the likelihood of cancer recurrence.

A. Multianalyte Assays with Algorithmic Analyses

We commend CMS for the significant efforts made in the past few years to gain a greater understanding of MAAA tests and their importance to clinical practice in oncology and other fields where their use helps to answer biologically complex diagnostic questions. We likewise commend and support CMS's continued policy position to set Medicare payment for these tests by gap-fill when the Medicare contractor determines the code is payable.

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Gap-fill remains the preferred method to establish payment amounts for MAAAs. Working on a case-by-case basis with these tests over the past several years, the Medicare Administrative Contractors (MACs) have developed approaches to set fair and reasonable payment for MAAAs.

B. Genomic Sequencing Procedures and other Molecular Multianalyte Assays

As defined by the codes set forth in CPT 2015, the GSPs subject to review by CMS for initial pricing by Medicare in 2015 range from tests that cover a few targeted genes to those that cover broad swaths of the human genome, including codes to report testing for the whole exome or genome, in order to identify clinically actionable variants revealed through multi-gene sequencing. These variants are genetic (i.e., germline) or genomic (i.e., somatic) abnormalities that can diagnose heart disease or better inform cancer treatment options, among other many clinically useful applications.

Because there are no analogues in the CLFS Tier 1 or Tier 2 codes that can be used as a cross-walk to describe the GSP tests subject to CMS's review, a gap-filling process remains the best option for determining the payment amount for these tests.

We agree with your decision to allow the MACs to gapfill the payment rates for these codes and commend your commitment to continuing to gather information about these tests to inform future decision making.

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The Coalition appreciates the thoughtfulness with which you have established the preliminary pricing determinations for these new CLFS Codes for CY 2015. If you have any questions about these comments, please contact me at 202.756.8148 or via electronic mail to ezimmerman@mwe.com.

Sincerely yours,



Eric Zimmerman