



July 8, 2013

Centers for Medicare and Medicaid Services
Baltimore, Maryland

Subject: 2013 Gap fill Payment Amounts

Dear Sir/Madam:

The American Association for Clinical Chemistry welcomes the opportunity to provide input to the Centers for Medicare and Medicaid Services (CMS) regarding the use of the gap-fill process for determining the payment rates for the new molecular pathology codes. Although AACC supports your decision to place the new codes on the clinical laboratory fee schedule, we are disappointed with the process employed to price them.

The agency chose to gap-fill rather than crosswalk the new tests. This has created confusion and uncertainty within the laboratory community as Medicare contractors have developed recommended fees with minimal input from testing providers. This has resulted in suggested payment rates for the molecular tests that generally range 20-30 percent less than last years stacking codes. In fact, the rates of some tests may be too low to cover the cost of the test.

One of the reasons for these low rates is the lack of transparency in the gap-fill process. We are concerned that many Medicare Administrative Contractors (MACs) did not fully seek and assess data on their own. These payment decisions will have a significant impact on providers and patients alike and therefore must be made in an open, interactive process to ensure that the payment rates are thoughtful and fair.

AACC is concerned that few MACs fully explained the rationale for their payment decisions. Only a handful of the MACs provided justifications as to how they reached their conclusions. Their submissions included little data on what formed the basis of their code adjustments. In fact, some contractors only listed the codes they were not covering rather than a thorough, thoughtful analysis of the cost data they reviewed and the rationale for the payment determination.

We are also concerned that what was initially a request by CMS to the AMA to provide clarity in the CPT codes for payers is becoming a mechanism for cost-cutting and denial of coverage. If not corrected, all private payers may follow CMS' lead, stifling innovation and denying personalized medical care to all but the wealthy. In addition, many of the specialty labs may be forced out of business due to the lack of timely or sufficient reimbursement.

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Furthermore, the coverage process should be handled separately from the pricing decision. In many instances, contractors made a summary notation of their intent not to cover the test when they announced their pricing (or lack of pricing) for the test. CMS has an extensive process for the establishment of Local Coverage Determinations. That is the process that contractors should use to make coverage decisions, as it allows for greater input from the public prior to a final decision.


In addition, some contractors did not submit prices to CMS for certain tests by declaring that the tests are used for screening in the absence of symptoms, or are confirmatory, and therefore not covered. This is inappropriate. No part of the gap-filling regulations deals with coverage for new tests. AACC believes it is preferable for all contractors to price all the codes, even if they do not intend to cover them. The coverage process should be handled separately from the pricing decision. CMS has an established process for the development of Local Coverage Determinations. That is the process that contractors should use to make coverage decisions, as it allows for greater input from the public prior to a final decision.

AACC recommends that CMS ensure that:

- patients have access to vital molecular tests;
- clinical laboratories are adequately paid for their testing services;
- local coverage decisions are to be made separately from pricing decisions;
- low reimbursement rates don't stifle the development of new technologies; and
- laboratories get paid for their services prior to the interim rates being established

By way of background, AACC is the principal association of professional laboratorians--including MDs, PhDs and medical technologists. AACC's members develop and use chemical concepts, procedures, techniques and instrumentation in health-related investigations and practice in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and medicine and applications to health care. If you have any questions, please call me at (410) 328-8672, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,



Robert Christenson, PhD
President, AACC