Association for Molecular Pathology

Promoting Clinical Practice, Translational Research, and Education in Molecular Pathology

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Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

CC: Marc Hartstein, Director Hospital and Ambulatory Policy Group
Comments submitted electronically to MoPathGapfillInquiries@cms.hhs.gov

Re: 2013 Gap Fill Payment Amounts to the Clinical Lab Fee Schedule

Dear Administrator Tavenner:

Thank you for the opportunity to submit these comments to the Centers for Medicare and Medicaid Services (CMS) as part of the official public record regarding the 2013 gap fill payment amounts. The Association for Molecular Pathology (AMP) is an international medical and professional association representing approximately 2,000 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 the new molecular pathology codes have a direct impact on their practice. As such, AMP submits these comments to explain its concerns about the gap fill process and recommendations moving forward.

No coverage since January 1, 2013:

Despite ample time of more than two years to complete the payment determination process prior to the new codes taking effect, CMS and its contractors failed to accomplish this need in a timely manner. Now more than half way into 2013, many of the Medicare Administrative Contractors (MACs) are not reimbursing claims using the new codes. Many laboratories have gone without coverage and reimbursement for their services since January 1, 2013. Had the stacking codes still been in place or CMS required that the MACs determine pricing by January 1, 2013, these laboratories would not face this challenging situation of providing much needed patient care without compensation for the services already rendered. This situation has resulted in laboratories making difficult decisions to drop tests from their menus and/or having to adapt to significant revenue shortages and financial pressures which can jeopardize their ability to remain in business.

To address the lack or reimbursement for services already rendered in 2013, AMP requests that CMS instruct the MACs to cover the molecular pathology codes and to retroactively pay laboratories from the start of 2013. The absence of CMS' finalized fees for the new molecular pathology codes should not result in the disruption of Medicare reimbursement.

Preliminary Payment Amounts Lower Than Costs:

In many instances, the prices established through the 2013 gap fill payment amounts are so low that they fail to even cover the cost of performing the test. Comparison of the gap fill prices with the practice expense and professional work data provided by the College of American Pathologists (CAP) as part of the American Medical Association Specialty Society RVS Update Committee (RUC) process demonstrates that almost all of the gap fill

prices fall short of the typical laboratory's costs for performing these tests. The AMP also conducted a survey of member laboratories that 1) demonstrated the challenge for laboratories in identifying all the direct and indirect components that are a part of the costs of performing these tests; and 2) demonstrated that, on average, the technical expenses are more in line with the CAP RUC data. Similar to AMP's previous concern, our members have pointed to this issue as forcing them to make difficult decisions about whether or not to continue providing these testing services. If these laboratories stop offering these tests or, in the extreme, have to close their laboratory, then Medicare beneficiaries and patients will have reduced access to potentially life-saving treatment and to the molecular pathology tests that guide these treatment options. For these reasons, AMP emphasizes to CMS that in its final determinations, the agency must address this issue of unsustainable reimbursement and increase the reimbursement levels.

Gap Fill Process Lacks Transparency and What Rationale Has Been Revealed is Flawed:

Last year, despite numerous public comments from AMP and other professional societies requesting placement of the new molecular pathology CPT codes on the Physician Fee Schedule (PFS) or, from others, requesting placement on the Clinical Lab Fee Schedule (CLFS) with payment amounts set using a crosswalk process, CMS has opted to place the CPT codes on the CLFS and set payment amounts using a gap fill methodology. AMP previously expressed concerns about the lack of transparency within the gap fill process and the general wisdom of pursuing that course. Nevertheless, AMP endeavored to make the gap fill process work, advising its members to cooperate with their Medicare Administrative Contractors to ensure accurate and fair pricing decisions. Our experience in the past six months has amply demonstrated the folly of using the gap fill process for pricing the molecular pathology codes and the difficulty in working with MACs. Despite the current public comment period, the gap fill process fails to provide adequate opportunities for experts and stakeholders to provide data and guidance. CMS did not provide adequate directions to the MACs on what data to collect; contractors did not understand nor did they have the resources to assemble appropriate costing data; the contractors did not have the resources to evaluate the costing data appropriately; and, finally, laboratories have difficulty accurately identifying all the cost information without specific direction. The premise that this process can lead to accurate and fair pricing policy cannot be supported.

We are also very concerned about the lack of data reported by the MACs for the Tier 2 codes. CPT Codes 81400 through 81408 are molecular pathology codes that were established for clinically useful procedures for lower volume tests. These codes describe nine levels of complexity ranging from the least complex procedure level 1 (81400) through the most complex procedure level 9 (81408) and have been arranged by the level of technical resources required to perform the service. These codes meet the strict criteria for category 1 placement that was established by the CPT Editorial Panel. However, we understand that the MACs have deemed that many of these services are experimental and investigational, therefore not reimbursed. It is evident that at this juncture, CMS does not have enough data to determine an appropriate rate for these CPT codes. Due to the lack of transparency, we also do not understand the rationale in deciding not to publish any values. The MACs and CMS had access to the values provided by the American Medical Association Specialty Society RVS Update Committee (RUC). In addition, we are also aware that several laboratories have provided cost information to their individual MACs as well as to CMS. We are proposing that CMS take additional time to review this information to ensure that appropriate values are assigned so that it does not become a financial burden for laboratories to provide services to Medicare beneficiaries.

AMP requests that CMS and the MACs provide explanation for how they decided on the interim pricing amounts and include a detailed rationale that has specific information on the data and calculations used to set the amounts. Having access to the pricing details as is the case with the RUC valuations provided by the CAP and the factors used in the decision making would not only result in more transparency, but benefit CMS in that stakeholders would be well positioned to provide useful and specific recommendations to the agency during this and other comment periods. AMP additionally asks CMS to provide additional data and information on the process utilized to set these amounts and to do so prior to finalizing the payment determination amounts.

The limited rationale posted on the CMS website is not extensive enough to provide adequate insight into the process, the data utilized, and how the contractors arrived at the resulting payment determinations. The methodology is so opaque that it is impossible to even determine if the range in prices for cystic fibrosis testing reflect a 23 mutation panel or a 73 mutation panel. Moreover, payment amounts should not anticipate possible lower cost technologies that may or may not be used for the various molecular pathology tests. At the May 28 NHGRI Genomic Medicine Meeting, Dr. Steve Phurrough addressed the fact that CMS does not change CLFS prices as it does on the PFS. He noted the agency is paying the same thing for a basic chemistry panel that it paid in 1969 and they are far cheaper now. One cannot assume that less expensive technologies will be used for molecular pathology tests anytime soon, and how much direct costs might decrease in the future. It is important to note that AMP previously submitted comments in 2012 expressing concern about the placement of the codes on the CLFS. Had they been placed on the Physician Fee Schedule, which has a well-articulated pathway to payment determinations, this concern could have been avoided as tests on the PFS are revalued periodically. For all of these reasons AMP requests that the RUC data, arrived at through a logical, vigorous process, be used to determine payment for the molecular pathology codes.

Current Payment Amounts Fail to Address the Professional Work Required to Provide Interpretation and a Clinically Actionable Report

In its December 28, 2012 comments to CMS regarding the final rule for the PFS, AMP expressed concern regarding the apparent notion in the rule that some of the molecular pathology procedures are "automated" and produce obvious results, precluding the need for professional work. On the contrary, molecular pathology procedures require translation of raw data into usable results for the treating physicians. Molecular pathology procedures are interpreted by physicians and specially trained doctoral scientists who are legally responsible for the accuracy of the results. The current payment amounts fail to account for the complex interpretations required and professional costs such as malpractice insurance premiums. In addition, the single HCPCS G-code, G0452, is not sufficient to recognize physician work, and a single code adequately recognize the varied professional effort required and recognized by the various molecular pathology codes. The varied professional effort is specifically recognized in the RUC data and, in the face of this specific information, it is irrational to suggest that a single code and reimbursement level is adequate and appropriate.

Conclusion

AMP appreciates the opportunity to submit these comments and AMP hopes to have the opportunity to continue this discussion with the agency in person. AMP offers its expertise as CMS finalizes the payment determinations and hopes that the agency will be responsive to the concerns outlined in this public comment letter. Specifically, AMP requests the following:

1. A meeting with Marc Hartstein, Director of Hospital and Ambulatory Policy Group.

2. Medicare retroactively reimburse laboratories back to January 1, 2013.

3. MACs and CMS increase the payment amounts to cover the cost of performing the test, including indirect costs.

4. CMS acknowledge and address the inadequacies of the gap fill process and, minimally, provide detailed information on the methodology and data used in the gap fill process.

5. In lieu of implementing a flawed gap fill process, CMS reconsider using the available RUC data to value the molecular pathology codes and place the codes on the PFS.

6. Provide additional opportunities for stakeholder comment and active participation in whatever pricing gap fill process is pursued.

Thank you for considering AMP's request. The Association looks forward to assisting CMS to ensure that the final payment determinations are appropriate and fair, and transparent. For additional information and to schedule a meeting with Mr. Hartstein, please contact Mary Williams, Executive Director of AMP, at 301-634-7921 or mwilliams@amp.org.

Sincerely,

Jennifer L. Hunt, MD, MEd
President