



August 10, 2016

Mr. Glenn McGuirk
Division of Ambulatory Services
Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: 2016 Preliminary Gapfill Payment Determinations for New GSP and MAAA CPT Codes

Dear Mr. McGuirk:

On behalf of the Personalized Medicine Coalition (PMC), I am pleased to submit comments on the Centers for Medicare & Medicaid Services (CMS)' 2016 Preliminary Gapfill Payment Determinations for Multianalyte Assays with Algorithmic Analyses (MAAA) and Genomic Sequencing Procedures (GSP).

The Preliminary National Limitation Amounts (Preliminary NLAs), if finalized, would represent drastic reductions in payment rates, by 30 – 90 percent, for tests deemed reasonable and necessary. To assure continued access to them, we request that the NLAs be adjusted to prevent such drastic reductions in the 2016 Final Gapfill Payment Determinations. Such adjustment will also help to avoid substantial changes in payment during the implementation of the Protecting Access to Medicare Act of 2014 (PAMA). As you know, Section 216 of PAMA is a re-pricing exercise that is just at the start of implementation. Getting this process right is critical to the future of personalized medicine.

Personalized medicine is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient. By combining the data from those tests with an individual's medical history, circumstances and values, health care providers can develop targeted treatment and prevention plans. Personalized medicine therefore has the potential to optimize delivery and dosing of treatments so patients can receive the most benefit with the least amount of risk, eliminating the difficulties of the trial-and-error process many patients endure to obtain the correct diagnosis and treatment for their condition.

PMC is an educational and advocacy nonprofit organization that promotes the understanding and adoption of personalized medicine to benefit patients and the health care system. We represent more than 240 institutions, including academic, patient, provider, and payer organizations as well as drug and diagnostic manufacturers and clinical laboratories. Given the missions and desires of the patient and health care stakeholder communities we bring together, PMC has a keen interest in CMS' 2016 Clinical Laboratory Fee Schedule (CLFS) Gapfill Payment Amounts.

Overall, PMC members are concerned that insufficient payment amounts threaten the sustainability of the laboratory industry and continued investment in the developing field of

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personalized medicine, thereby removing the promise of sustaining innovation in health care and possibly lowering overall costs by eliminating unnecessary and/or ineffective treatments.

Specifically, this proposed gapfill payment schedule:

- *Confuses stakeholders due to the lack of transparency in the gapfill process*
- *Reduces the quality of patient care and patient access*
- *Threatens the future of health care by not addressing potential unintended consequences*

I. PMC is concerned about the level of stakeholder engagement and the lack of transparency in the gapfill process.

PMC is concerned with how the gapfill process unfolded in this case. To determine gapfill amounts, Medicare Administrative Contractors (MACs) should use the four criteria consistent with 42 C.F.R. 414.508(b)(1). Particularly, payments should cover the resources required to develop and perform these tests, including reasonable costs for supplies, equipment, clinical labor, test performance, operating a clinical laboratory, research and development, and the continuous process improvements required for testing and, often, test interpretation. In addition, consistent with Section 216 of PAMA and current gapfill criteria, significant weight should be given to rates established by other payers for these tests, since some MACs have more experience with the tests than others. For example, current Medicare payment rates for those MAAA gapfill tests that have had long-established payment rates under unlisted codes in the past were established through an open process with local MACs that cover the tests that addressed the gapfill criteria. Those rates should be upheld.

To bring transparency to this process, CMS should require all MACs to disclose pricing methodology and describe the data used to determine their new payment schedule. Furthermore, we ask that this process be revisited and revised to be as transparent as possible. One suggestion is that CMS require MACs to engage with stakeholders in their jurisdiction, so that MACs can make educated decisions on the tests offered to define accurate and reasonable prices. We ask for significant stakeholder engagement, including public meetings, at each step of a new process resulting in payments that are evidence-based, transparent, and reflect the costs associated with these tests.

PMC understands that other stakeholders are developing models to better evaluate the resources required to perform these tests and more accurately reflect the relative amounts of work involved as the volume of genomic sequences analyzed increases. We encourage CMS to consider these proposals, and to ensure that the final gapfill pricing for tests provides an adequate basis for their continued offering to Medicare and Medicaid beneficiaries.

II. PMC is concerned about the impact that inadequate payments will have on patient access to high-quality care.

PMC is concerned that inadequate payments are, in essence, a non-coverage decision with the potential to negatively impact treatment decision-making by patients and their health care providers. Coverage decisions should be determined through a separate process. De facto non-coverage through payment decisions is not appropriate.

Limiting access to personalized medicine will delay getting the right treatment to the right patient. It will lock in our current one-size-fits-all, trial-and-error system that all stakeholders, including payers but most importantly patients, would like to move beyond. Identifying the right treatment for the right patient the first time will enable the delivery of high-quality, more efficient, higher value care, which is better for patients and better for the health system.

We must also acknowledge PAMA implementation here. CMS has worked with stakeholders on the proposed rule and adjusted it before publishing the final rule. Implementation has begun. Drastically altering current payment rates for covered tests negatively impacts that process and thus is in violation of the spirit of the law.

III. PMC is concerned about the unintended consequences of the proposed gapfill payments on the future of personalized medicine.

Personalized medicine is changing how medicine is practiced. Its impact is notably evident in serious and life threatening conditions that have previously lacked efficacious treatments. Through the use of innovative diagnostics, health care quality is increasing while the health care system becomes more efficient. However, poorly developed and executed policy decisions, like the gapfill payment process, will negatively impact health care quality improvements by discouraging the development of new tools in the life sciences.

We are also concerned about the consequences for patient access to the tests they require. While large laboratories have diverse menus of services, PMC's membership includes labs that focus exclusively on personalized medicine diagnostics. With payments set at markedly lower levels, we fear these labs will go out of business and if their technology is not acquired, the test will no longer be offered; a danger that is particularly important for those with rare conditions. This disruption will endanger patients' and their health care providers' access to testing, ultimately hindering the benefits of personalized medicine in health care.

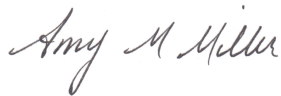
We ask that CMS consider these unintended consequences of gapfill payment decisions and other policies as they work through this issue.

Conclusion

Coverage and payment decisions should be separate processes. When CMS decides to cover a test, we ask that the payment reflect the reasonable cost of performing that test in a high-complexity laboratory by highly trained professionals, as well as covering the associated research and development costs and capital returns required to attract innovators to the industry. Without this support, the future ability of personalized diagnostics to improve patient care may be compromised and, quite simply, new tests will not be developed and important currently offered tests may be discontinued. Thus, patient access to new and improved treatments will suffer.

PMC appreciates the opportunity to provide comments on the 2016 Gapfill Payment Amounts. If you have any questions about these comments, please contact me at 202-589-1770 or via e-mail at amiller@personalizedmedicinecoalition.org.

Sincerely yours,



Amy M. Miller, Ph.D.
Executive Vice President