



October 22, 2018

Dr. Carol Blackford
Director, Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services
Mail Stop C5-07-22
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Calendar Year 2019 Medicare Clinical Laboratory Fee Schedule Preliminary Determinations

Dear Dr. Blackford,

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprised of more than 230 institutions and individuals across the health care spectrum, is writing to express concern with the preliminary Clinical Laboratory Fee Schedule (CLFS) determinations released on September 21, 2018, by the Centers for Medicare & Medicaid Services (CMS) for Calendar Year (CY) 2019. We believe the preliminary determinations may undermine personalized medicine.

Personalized medicine is an evolving field that uses diagnostic tools to identify specific biological markers, often genetic, to help determine which medical treatments and procedures will be best for each patient. By combining this information with an individual's medical history, circumstances, and values, personalized medicine allows doctors and patients to develop targeted prevention and treatment plans.

Personalized medicine is helping shift the patient and provider experience away from trial-and-error and toward a more streamlined process for making clinical decisions, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC's members are leading the way in personalized medicine and recommend that patients who may benefit from this approach undergo appropriate testing and tailored treatment as soon as possible during their clinical experiences.

All of PMC's members share the goal of making personalized medicine possible. For this reason, we have a keen interest in payment determinations for tests that facilitate its delivery. The proposed CY 2019 payment rates for a number of tests considered by CMS are insufficient and at times contrary to current coverage policies. We believe the preliminary determinations must be revisited.

Statement of Neutrality

Many of PMC's members will present their own responses to CMS' preliminary CLFS determinations for CY 2019 and will actively advocate for those positions.

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PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance. PMC's comments are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments and positions related to specific products.

Inadequate payments for tests may impact patient access to optimal care.

PMC is concerned that inadequate payments set forth in the preliminary CY 2019 CLFS determinations will influence treatment decision making by patients and their health care providers. Many laboratories will not be able to provide certain tests to Medicare beneficiaries because of their low rates. A laboratory's inability to furnish these tests removes options for patient management that might be more clinically appropriate for an individual patient's condition. Minimizing the availability of tests will delay providers in getting the right treatment to the right patient.

PMC members are also concerned that insufficient payment amounts proposed in the preliminary CLFS determinations for CY 2019 threaten the sustainability of the laboratory industry and continued investment in the developing field of personalized medicine. These threats to an important industry and field ripe for continued investment jeopardize the promise of sustained innovation in health care and of lowering overall costs by eliminating unnecessary and ineffective treatment.

CMS has an opportunity to foster progress in health care by avoiding conventional payment policies that would blunt the adoption of personalized medicine. A system that limits choices of tests and treatments is one that all stakeholders, including patients and providers, would like to transcend. Identifying the right treatment for the right patient the first time enables the delivery of high-quality, more efficient, higher value care, which is better for patients and better for the health system. PMC requests that CMS establish CY 2019 payment rates that are sufficient to cover the resources required to develop and furnish diagnostics that will inform personalized treatments. If finalized, many of the preliminary determinations would place laboratories in a difficult financial position and impact patient access to optimal care now and in the future.

Preliminary determination contradicts a CMS national coverage determination.

PMC recognizes that national coverage policies should be determined through a separate process; however, insufficient rates proposed for Food and Drug Administration (FDA)-approved next-generation sequencing (NGS) tests with companion diagnostic claims in CY 2019 are, in essence, non-coverage policies made through payment decisions. In 2017, CMS worked with stakeholders on a national coverage determination (NCD) for the use of NGS tests in Medicare beneficiaries with advanced cancer. PMC and individual members of the Coalition were active throughout the NCD process because that decision established a significant coverage and regulatory requirement for an essential personalized medicine diagnostic. CMS published the final decision memo requiring FDA approval or clearance and a companion diagnostic claim. Implementation of this NCD has begun.

The final NGS NCD did not require a specific sequencing technology or number of genes for coverage, but the preliminary CY 2019 CLFS bases crosswalk for NGS tests with a companion diagnostic claim on "similar sequencing technology to identify sequence variants." This crosswalk contradicts CMS' NCD coverage criteria and requirement. Adopting this crosswalk would drastically alter current reimbursement rates for tests covered under the NCD, limiting independent laboratories' ability to adopt and supply tests for Medicare beneficiaries with advanced cancer. We also fear that the precedent set by reversing

requirements of the NCD will deter future efforts to develop FDA-approved NGS companion diagnostic tests for new therapies.

PMC urges CMS to crosswalk FDA-approved NGS tests with companion diagnostic claims in CY 2019 to a more appropriate test or, at a minimum, consider gapfill. This position is supported by leading clinical societies, in addition to PMC.

Conclusion

Thank you for the opportunity to provide feedback on the CY 2019 preliminary CLFS determinations. PMC appreciates your careful consideration of our comments. We welcome the opportunity to serve as a resource for you. If you have any questions about the content of this letter, please contact me at 202-589-1769 or cbens@personalizedmedicinecoalition.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Cynthia A. Bens". The signature is fluid and cursive, with the first name being the most prominent.

Cynthia A. Bens
Senior Vice President, Public Policy