



February 10, 2020

Seema Verma, MPH
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS-1715-P
7500 Security Boulevard
Mail Stop C4-26-05
Baltimore, MD 21244-1850

RE: Information for Consideration in Future Medicare Physician Fee Schedule (MPFS) Rulemaking

Dear Administrator Verma,

Bracco Diagnostics Inc. (Bracco) offers a full line of diagnostic imaging products, including contrast agents, injectors, and radiopharmaceuticals. Our Nuclear Medicine business unit markets quality radiopharmaceuticals that assist in the diagnosis and treatment of disease for Medicare beneficiaries. Bracco's featured product portfolio for nuclear cardiology departments includes CardioGen-82[®] (Rubidium Rb 82 Generator), the market-leading, generator-based radiopharmaceutical for positron emission tomography (PET) myocardial perfusion imaging (MPI), the most common form of Cardiac PET imaging, and an important diagnostic tool for coronary artery disease (CAD), the leading cause of mortality in the U.S.

Bracco appreciates the opportunity to supply the Centers for Medicare & Medicaid Services (CMS) with information for future rulemaking.

In implementing work and Practice Expense (PE) inputs for the newly redefined myocardial PET services, during the CY 2020 MPFS proposed rulemaking process, CMS proposed technical component (TC) relative value units (RVUs) that represented significant reductions from carrier-based TC pricing. In our previous comments to CMS, Bracco stressed the importance of Cardiac PET imaging providers having an adequate payment rate in order to continue to provide access to this clinically important procedure. Bracco outlined concerns with the underlying PE inputs that produced the TC RVUs and provided information and rationales to support those concerns. We thank the Agency for being responsive and receptive to those concerns, ultimately choosing to revert TC payment to contractor pricing for CY 2020. We are aware that the medical specialty societies whose members utilize Cardiac PET, i.e. -- ASNC, SNMMI and ACC -- recently met with the Agency and have provided additional information for consideration. As a leading pharmaceutical company dedicated to this space, however, we believe that additional work is necessary to correctly capture

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the practice expense necessary for myocardial positron emission tomography (PET) services provided in the physician office setting and feel there are still significant indirect practice expense obstacles that cannot be immediately solved.

Indirect Practice Expense (PE) Costs

In the CY 2020 final rule, CMS clarified that maintenance and other infrastructure costs related to placement of equipment in a building are considered indirect PE. While it was helpful to receive clarification from the agency that such costs are meant to be accounted for elsewhere in the PE methodology, for the reasons described above, we are concerned that the formula and the current inputs will continue to be problematic for this modality, requiring additional refinement in order to have correct inputs.

Recommendation

We believe that additional refinements to the process for accounting for Cardiac PET expenses are warranted. Accordingly, until additional information is available and appropriate actions can be taken to implement recommendations, Bracco believes maintaining the status quo of contractor pricing for the TC of these services is a reasonable solution.

Thank you for consideration of this additional information and these comments as you begin preparations for future rulemaking. Bracco appreciates CMS's willingness to find meaningful solutions to identify appropriate inputs for myocardial PET services.

Respectfully,

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