



The Council on Radionuclides and Radiopharmaceuticals, Inc.

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VIA EMAIL

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Attention: Division of Practitioner Services, Potentially Misvalued Codes
7500 Security Boulevard
Baltimore, MD 21244-1850

**RE: Valuation of Myocardial Positron Emission Tomography (PET) Procedures
in Medicare Physician Fee Schedule Rule for CY 2021**

Dear Ms. Verma:

The Council on Radionuclides and Radiopharmaceuticals Inc. (CORAR) appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) in advance of the proposed Medicare Physician Fee Schedule (PFS) rule for calendar year 2021 (Proposed 2021 PFS Rule), focusing on valuation of myocardial positron emission tomography (PET) procedures.

CORAR represents the developers, manufacturers, and radiopharmacies that provide RPs to physician offices and imaging centers for the diagnosis and treatment of Medicare beneficiaries and other patients. Nuclear medicine imaging procedures are a safe and non-invasive way to image the body through the use of specialized cameras and software applications in conjunction with diagnostic RP drugs that are introduced into the body. Nuclear medicine imaging with RPs goes a step beyond other imaging tests such as X-rays and MRIs because, in addition to illustrating an organ's anatomy, it can demonstrate an organ's function. This is critical information that otherwise would not be available or available only through the use of more expensive, invasive tests or surgery. Thus, the benefits of nuclear medicine imaging are especially important for Medicare beneficiaries who may not tolerate more invasive tests or surgery.

CORAR commends CMS for not adopting its proposed reductions to practice expense (PE) and work relative value units (RVUs) for myocardial PET procedures for 2020. CMS invited comments on payment for these services for consideration in future rulemaking. As discussed below, we urge CMS to ensure it maintains appropriate RVUs for PET procedures to preserve beneficiary access to these services as it develops the Proposed 2021 PFS Rule.

I. Background: 2020 PFS Rulemaking

In the proposed 2020 PFS rule, CMS proposed steep reductions in the work and PE RVUs for myocardial PET procedures, particularly:

CPT 78491 -- Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic)

CPT 78492 -- Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic)

The American College of Cardiology (ACC), American College of Nuclear Medicine (ACNM), the American Society of Nuclear Cardiology (ASNC), Cardiology Advocacy Alliance (CAA) and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) estimated that the proposed inputs could reduce payment for the technical component (TC) for some myocardial PET services by up to 80%.

Much of the proposed decline in RVUs was attributed to CMS's proposal to move away from contractor pricing of the TC of nuclear medicine PET services and to instead adopt "active pricing" for these procedures. For equipment items ER110 (PET Refurbished Imaging Cardiac Configuration) and ER111 (PET/CT Imaging Camera Cardiac Configuration), CMS proposed adopting a 90% -- rather than 50% -- equipment utilization rate based only on general equipment utilization assumptions for expensive diagnostic imaging equipment. With regard to work values, CMS proposed to disregard the AMA RUC¹ recommendations and instead adopt sharply lower work RVUs based on a questionable total time ratio methodology.

In our comment letter on the proposed 2020 rule, CORAR expressed our concerns that the proposed rule would significantly undervalue this equipment, especially relative to contractor pricing. We recommended that CMS restore the 50% utilization assumption for ER110 and ER111 and work closely with the specialty societies to develop more accurate inputs. We likewise urged CMS to defer adoption of the proposed work RVUs for 2020 and to collaborate with the specialty societies to reevaluate these codes and develop a consensus on accurate RVUs. Finally, to the extent that CMS adopted significant reductions in the RVUs, we requested that CMS observe the Protecting Access to Medicare Act of 2014 (PAMA) requirement that reductions of in total RVUs of 20 percent or more must be phased in over multiple years to mitigate provider disruptions and preserve patient access to these critical services.

CORAR was pleased that CMS did not adopt these cuts to myocardial PET procedure valuations in the final 2020 PFS rule. In particular:

- CMS agreed to delay active pricing of the TC of nuclear medicine PET services in 2020, which would have resulted in deep payment cuts, in "the interest of maintaining payment stability and protecting patient access to these important services." CMS noted that "there is substantial work to be done to assure the new valuations for the TCs of these codes accurately reflect the technical inputs," and CMS agreed to review inputs submitted by the public.
- Based on information submitted by commenters, CMS did not adopt its proposal to assume a 90% utilization rate for the ER110 and ER111 equipment items; instead CMS maintained the default 50% utilization rate assumption for both items.
- CMS agreed to use the RUC recommendations rather than its proposed lower RVUs, in "consideration of the public comment, and in the interest of payment stability and protecting patient access for these services."

¹ American Medical Association (AMA)/Specialty Society Relative Value Scale Update Committee (RUC).

Together these final policies were a significant improvement over the proposed rule, and we commend CMS for its consideration of the data submitted by stakeholders and its responsiveness to our comments.

II. Comments in Preparation for the Proposed 2021 PFS Rule

CORAR appreciates CMS's solicitation of input on myocardial PET procedure pricing in advance of the Proposed 2021 PFS Rule. We urge CMS to continue the 50% utilization assumption for ER110 (PET Refurbished Imaging Cardiac Configuration) and ER111 (PET/CT Imaging Camera Cardiac Configuration), which is supported by workflow data submitted to CMS. We agree with CMS that "there is substantial work to be done to assure the new valuations for the TCs of these codes accurately reflect the technical inputs." CMS should ensure stable values for these procedures while this work is ongoing to protect patient access. More broadly, we urge CMS to carefully collaborate with the specialty societies with regard to both the work and PE RVUs for these procedures so that the valuations accurately and fully capture the resources associated with these procedures.

In the final 2020 rule, CMS indicated that it would not consider itself bound by the provision of Protecting Access to Medicare Act of 2014 (PAMA) requiring phase-in of significant RVU reductions if the RVU change results from a shift from contractor-priced status to active pricing status. CMS provided no statutory support for this assertion – only that it "believes" that moving from contractor-priced status to active pricing status "constitutes a 'revised code'" that is exempt from the PAMA rule, rather than a change to an existing code.

We respectfully disagree with this new interpretation, and believe such a policy is not supported by the actual statutory language or CMS's prior final rule for CY 2019, which CMS cited in the 2020 final rule preamble.

Section 1848(c)(7) of the Act, as added by section 220(e) of PAMA, provides that:

Effective for fee schedules established beginning with 2017, for services that are not new or revised codes, if the total relative value units for a service for a year would otherwise be decreased by an estimated amount equal to or greater than 20 percent as compared to the total relative value units for the previous year, the applicable adjustments in work, practice expense, and malpractice relative value units shall be phased-in over a 2-year period."

In the 2020 final rule, CMS directed readers to the 2016 PFS final rule for additional information, but that rulemaking fails to justify a blanket exclusion from PAMA phase-in requirements when CMS adopts active pricing for an unchanged code. Specifically, in the 2016 rulemaking, CMS implemented this policy by applying the phase-in "to all services that are described by the same, unrevised code in both the current and update year, and to exclude codes that describe different services in the current and update year." CMS stated that this approach excludes as new or revised:

- Codes for which the descriptors were altered substantially for the update year to change the services that are reported using the code.
- Codes that describe a different set of services in the update year when compared to the current year by virtue of changes in other, related codes.
- Codes that are part of a family with significant coding revisions.
- Codes with changes to the global period, since the code in the current year would not describe the same units of service as the code in the update year.

These exclusions were intended to address situations in which “there is no practical way to phase-in changes to RVUs that occur as a result of a coding change for a particular service over 2 years because there is no relevant reference code or value on which to base the transition.”

We have reviewed CMS’s policy adopted in the 2016 final rule, and observe that none of CMS’s examples of a *revised* code apply to a situation in which CMS moves an established procedure from contractor-priced status to active pricing status. That is, there is no altered code description, no different set of services, no significant coding revisions within the family, nor changes to the global period. Furthermore, CMS has reference values (e.g., carrier prices, paid claims data) for these established procedures that could be used as a reference for purposes of determining the maximum one year adjustment under PAMA.

Thus, to the extent that CMS adopts myocardial PET code RVUs that represent a significant reduction as a result of adoption of active pricing, we reiterate our request that CMS observe the statutory PAMA standard. Specifically, in such a case, any reduction of 20% or more in total RVUs must be phased in over multiple years to mitigate provider disruptions and preserve patient access to these critical services.

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CORAR appreciates CMS’s careful consideration of our comments. I would be happy to answer any questions you may have and can be reached at (202) 547-6582 or michael.guastella@corar.org.

Sincerely,



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cc: *Council on Radionuclides and Radiopharmaceuticals, Inc.*
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