



AMERICAN  
COLLEGE of  
CARDIOLOGY



February 10, 2020

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health & Human Services  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Submitted Electronically to: [medicarephysicianfeeschedule@cms.hhs.gov](mailto:medicarephysicianfeeschedule@cms.hhs.gov).

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

Dear Administrator Verma:

The American College of Cardiology (ACC), American Society of Nuclear Cardiology (ASNC), and Society of Nuclear Medical and Molecular Imaging (SNMMI) appreciate the opportunity to supply the Centers for Medicare & Medicaid Services (CMS) with information regarding payment for myocardial positron emission tomography (PET) services for future rulemaking.

In implementing work and practice expense (PE) inputs for a family of newly (re)defined myocardial PET services, CMS proposed technical component (TC) relative value units (RVUs) that represented significant reductions from carrier-based TC pricing. On behalf of patients and clinicians, the societies outlined concerns with the underlying PE inputs that produced the TC RVUs and provided documents 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 while additional effort is made to ensure the new valuations for TC RVUs accurately reflect the technical inputs. We believe additional work is necessary to correctly capture the practice expense necessary for myocardial PET services provided in the physician office setting. Solutions to indirect practice expense obstacles that cannot be immediately solved and new information regarding direct practice expense inputs are included here for consideration.

### **Indirect 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. It was helpful to receive clarification from the Agency that such costs are meant to be accounted for elsewhere in the PE methodology. However, we are concerned the formula and the

current inputs will continue to be problematic for this modality, requiring additional refinement to correct inputs.

One solution the societies have explored is execution of a supplemental indirect PE survey. Myocardial PET was a smaller modality when the most recent Physician Practice Expense Information Survey (PPIS) was executed in 2007-2008, and these costs are almost certainly underrepresented in that survey data. Only 16 nuclear medicine PE/HR surveys were completed. Acquisition of current data for these indirect costs could provide a better foundation for myocardial PET or other nuclear imaging services. Though some alteration in the PE formula may also be necessary so these costs are not diluted by indirect PE per hour data for the broader specialties that provide these services. However, as CMS knows from efforts to collect this type of data from the PPIS of last decade, it is a long and challenging process to complete a survey of this nature.

Furthermore, CMS has already contracted with The RAND Corporation to convene a technical expert panel (TEP) to explore potential improvements to CMS' PE allocation methodology and the data that underlie it. The societies believe there may be recommendations in this report that would influence a course of action to ensure correct accounting of indirect costs related to myocardial PET. CMS and other stakeholders may choose to respond and take actions that would clarify a path forward but are not envisioned at this time. After that report is published, subsequent actions may be outlined in response that could facilitate more accurate payment for myocardial PET. Currently, it would be premature to execute a supplemental indirect PE survey of any sort. The societies recommend the status quo of contractor pricing for the TC of these services is a reasonable solution until such time as recommendations from that report and more accurate inputs can be developed.

### **Direct PE Inputs**

Since publication of the CY 2020 proposed rule in July, the societies have pursued invoices and documentation to confirm or refine pricing of direct PE inputs. Most information was collected and submitted as comments on the proposed rule. Most additional information on existing inputs shared since October aligns with those submissions and CMS revisions in the final rule. At this time, we do not recommend any further revisions to pricing for the existing camera equipment inputs.

### **Germanium-68 rod source kits**

As referenced in a prior comment letter on the CY 2019 final rule, our members have indicated that a piece of equipment, (ER044) nuclide rod source set, was inadvertently excluded from Myocardial PET-only CPT codes 78459, 78491, 78492, and 78432. Additionally, the current input ER044 has an incorrect life as these sources are replaced every nine months to one year, not every five years as currently in the CMS data base. The Ge-68 rod has a half-life of 270 days; therefore, the rod life is a maximum of one year or earlier and not five years. We request CMS update its file and correct the life of ER044 to 0.75 years, as well as add it to the direct inputs for the CPT codes listed above.

The Germanium rods are required in all dedicated PET scanners for the purpose of attenuation correction, which is required for a PET scanner. Comparatively, this attenuation correction is executed by the CT portion of a PET-CT camera. As discussed above, the Germanium rods have a 270-day half-life, are used to produce transmission maps and are necessary in PET scanners to reduce artifacts. The Germanium rods must be replaced every 9 months to one year. Member experts from our societies confirm there are typically (most commonly) two germanium rod sets required for a PET camera (though some cameras require three rod sets). For comparison, single photon emission computed tomography (SPECT) systems that use Gadolinium 153 rod sources for attenuation correction typically require one rod set per camera head. The Germanium rods themselves are necessary for dedicated PET in the same way software is necessary to operate the camera; we do not believe this cost is part of overhead. The service contract that includes the labor to execute the installation would be an overhead expense and should be considered separate. Therefore, we recommend the cost of the rods and not the cost of the installation to be added as direct inputs to CPT codes 78459, 78491, 78492, and 78432.

The amount of equipment time necessary for these rod sets would be the same as the time the PET scanner is in use for each of the CPT codes listed above. The societies ask CMS to add this piece of direct equipment as an input for PET since it is already in the CMS equipment list. We do not believe there have been changes to the cost of ER044 and have confirmed that cost per rod set in some attached invoices obtained and explained in the attached excel and PDF. CMS's current pricing of ER044 is \$1977.2497 as listed in the 2020 final rule. Consultation with our experts aligns with that price for each rod set.

The attached excel and PDF are the invoices obtained from our members. While many are in differing formats, we have confirmed the typical costs for a five millicurie Ge-68 rod source is roughly \$2,000. See the three attached invoices: Invoice A (\$1,905.29), Invoice B (\$3,194.10) and Invoice C (\$1,500.00). This confirms CMS's current input price of \$1,977.25.

Information from equipment manufacturers, independent diagnostic testing facilities, and our members confirms that vendors install these rods; it is not something internal staff can perform. While we were not able to obtain invoices that break out the install costs from the rod source set, we did get information that \$10,000 is commonly the price to install two rod sets. Therefore, we removed those costs, but we do include the costs of shipping and delivery as those are direct costs for the rod sources.

### **Maintenance Costs**

The equipment cost per minute calculation,  $(1/(\text{minutes per year} * \text{usage})) * \text{price} * ((\text{interest rate}/(1-(1/((1 + \text{interest rate})^{\text{life of equipment}})))) + \text{maintenance})$ , includes a factor for maintenance that is 5% of the equipment purchase price. Through the process of collecting invoices for costs, we have consistently seen the 5% factor underrepresent the maintenance and service needs to keep these complex machines running. While the

expense is considerable, \$26,380 to keep a PET camera (ER110) functioning over the course of a year is still inadequate. The societies suggest that in the same way equipment useful lifespan and utilization percentages be individualized to each piece of equipment. It may be necessary—at least in some instances—for the equipment maintenance factor to flex with the documented needs of the individual piece of equipment. This may be something the RAND TEP could further explore as part of its work.

### **PET Generator (Rubidium)**

As noted in previous comments, CMS applied a PET Generator invoice to create a new equipment input, ER114, named “PET Generator (Rubidium)”. With the emphasis on identifying and correcting flawed and underpriced inputs, societies failed to alert CMS that the costs for the purchase of the PET Generator are captured elsewhere when offices bill Healthcare Common Procedure Coding System (HCPCS) supply code A9555, *Rubidium rb-82, diagnostic, per study dose, up to 60 millicuries*. While some commenters highlighted the costs of the PET Generator, the societies do not believe those stakeholders realized those costs are separately billed. As such, the societies recommend CMS remove equipment item ER114 to avoid incorrect duplication and felt it was appropriate to restate this recommendation here.

### **Conclusion**

Thank you for consideration of this additional information and these comments as you begin preparations for future rulemaking. The societies appreciate CMS’ efforts to find meaningful solutions to identify accurate technical inputs for myocardial PET services.

Sincerely,



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ASNC President



Vasken Dilsizian, MD  
SNMMI President



Richard Kovacs, MD, FACC  
ACC President

Attachments