October 2, 2020

Submitted electronically via: https://www.regulations.gov

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: Medicare Program; CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies [CMS-1734-P]

Dear Administrator Verma:

The American Society of Nuclear Cardiology (ASNC) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule on CY2021 Revisions to Payment Policies under the Physician Fee Schedule (PFS) as published in the *Federal Register* on August 17, 2020.

ASNC is a 4,500 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology and cardiovascular computed tomography, develops standards and guidelines for training and practice, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

ASNC offers comments on the the following:

- CY 2021 Conversion Factor
- Myocardial PET Equipment Inputs
- Proposed Removal of NCD #220.6.16 FDG PET for Inflammation and Infection
- Medicare Appropriate Use Criteria Program for Advanced Diagnostic Imaging
- Practice Expense RVU Updates
- Supervision of Diagnostic Tests by Certain Non-physician Providers

CY 2021 Conversion Factor

The planned significant decrease in the CY 2021 Medicare conversion factor could not come at a worse time for physicians across the country. **ASNC urges the Agency to take immediate actions to delay or**

mitigate the cut arising from budget neutrality requirements while allowing the previously finalized evaluation and management (E/M) code policies to take effect on January 1, 2021.

The cut to the conversation factor will be profound for cardiologists for whom diagnostic imaging, including nuclear cardiology, represents a significant portion of their mix of services. Federal subsidies have offset the worst of the economic impact on physicians, but the financial losses persist as many physician practices are unable to return to pre-COVID patient capacity due to staffing shortages, and longer turn-around times between patients to allow for proper COVID-related safety and disinfection protocols to take place. Additionally, practices are coping with the cost of enhanced personal protective equipment and added human resource costs associated with COVID-19 testing prior to certain medical tests and procedures.

Beyond the challenges caused by the pandemic, Medicare payments have failed to keep up with inflation since the inception of the PFS in 1992. The planned decrease in the 2021 conversion factor will be below the 1994 conversion factor of $32.9050 — which is worth approximately $58.02 today. Other sectors of the health care delivery system do not face the same problems.

With spending growing faster for privately insured patients than for Medicare beneficiaries — 24 percent and 10 percent, respectively, between 2014 and 2018[1] — the risk is an economic disincentive for providers to expand access to our growing Medicare beneficiary population. And when coupled with the devastating toll of the pandemic on physician practices, declining reimbursement increases the likelihood of more provider consolidation at a greater cost to the health care system.

ASNC respectfully asks the Agency to use all regulatory authorities at its disposal, including the public health emergency, to prevent or mitigate the severity of the pending payment cuts before the new E/M policies take effect.

MYOCARDIAL PET EQUIPMENT INPUTS

Following publication of the CY 2020 PFS final rule, ASNC and other stakeholders presented the Agency with additional information regarding the direct practice expense inputs for Myocardial PET services — CPT codes 78432, 78459, 78491, and 78492. On behalf of patients and clinicians, ASNC thanks the Agency for being responsive to our recommendations.

Maintain Contractor Pricing

ASNC supports maintaining contractor pricing for the technical components for CPT codes 78432, 78459, 78491, and 78492 for CY 2021 and asks CMS to finalize this proposal. ANSC asks that contractor pricing be maintained for CY 2021 which will allow for payment predictability that will, in turn, ensure continued patient access to this important imaging technology.

Myocardial Perfusion PET has high diagnostic accuracy and is useful in recognition of multi-vessel coronary artery disease due to its high sensitivity. It provides consistent, high quality images with high spatial resolution and robust non-uniform soft tissue attenuation. PET myocardial perfusion imaging

[1] Medicare Payment Advisory Commission Presentation September 3, 2020. Accessed on September 24, 2020 at http://www.medpac.gov/docs/default-source/meeting-materials/medpac_context_sept_2020.pdf?sfvrsn=0

also uses less radiation than conventional SPECT imaging and is particularly useful in several special populations including obese patients or those with challenging body habitus, as well as those who have had uncertain or discordant results from other types of stress tests. Myocardial perfusion PET imaging provides powerful cardiac risk assessment and is capable of assessing absolute quantitation of myocardial blood flow (PET Flow) that provides even more robust risk stratification.

As ASNC has conveyed in past comments to the Agency, there are costs associated with myocardial PET that are not accounted for by CMS' practice expense methodology, including the software and hardware required for absolute quantitation, as well as infrastructure costs associated with installation and maintenance of PET machines, such as items required by the Nuclear Regulatory Commission or state authorities. These items add hundreds of thousands of dollars to the cost of providing myocardial PET. CMS payments should account for these costs. We acknowledge CMS' direct practice expense accounting methods do not capture these costs, which would need to be accounted for elsewhere in the practice expense methodology. As such, **contractor pricing should be maintained for the technical components of these codes until there can be an adequate accounting of all costs associated with the delivery of Myocardial PET.**

Nuclear Rod Source Set

ASNC supports CMS' proposal to update the price for the nuclide rod source set (ER044) equipment to $2,081.17 based on averaging together the price of submitted invoices, after removing the shipping and delivery costs according to the Agency's standard pricing methodology. **We also support adding, as proposed, the ER044 equipment to CPT codes 78432, 78459, 78491, and 78492, assigning the same equipment time utilized by the "PET Refurbished Imaging Cardiac Configuration" (ER110) equipment in each service.** As ASNC previously commented, ER044 was inadvertently omitted from the PET-only CPT. We thank the Agency for recognizing the need to correct this oversight and ask that the proposal be finalized.

Useful Life of ER044

In a letter to the Agency in February 2020, ASNC, the Society of Nuclear Medical and Molecular Imaging, and the American College of Cardiology commented that nuclide rod source kits are replaced every nine months to one year.

ASNC asks CMS to finalize its proposal to update the useful life of the ER044 equipment to one year. While we asked CMS to use 0.75 years, ASNC recognizes that one year is in accordance with the Agency's policy to treat equipment useful life durations of less than one year as having a duration of one year.

PET Generator (Rubidium)

ASNC supports the proposal to remove the "PET Generator (Rubidium)" (ER114) equipment from the CMS database to avoid incorrect duplication of the cost of this equipment item.

CMS applied a PET Generator invoice to create a new equipment input, ER114, named "PET Generator (Rubidium)." However, 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.

PROPOSED REMOVAL OF NCD #220.6.16 FDG PET FOR INFLAMMATION AND INFECTION

ASNC strongly supports the Agency's proposal to remove the National Coverage Determination (NCD) #220.6.16 FDG PET for Inflammation and Infection using the expedited administrative process established in 2013 to remove NCDs older than 10 years, thereby allowing the local Medicare Administrative Contractors (MACs) to determine coverage.

As ASNC representatives conveyed during an April 2, 2019 meeting with CMS officials, the PET NCDs for Cardiac and Infection/Inflammation Indications are outdated and the relevant cardiac NCD is based on outdated technical assessments and literature from the 1990s. Since the NCD was published in 2008, a large body of data have been published supporting medical necessity of FDG PET for sarcoidosis — an inflammatory disease that can affect one or more organs of the body, including the heart.

This disease is characterized by the growth of tiny collections of inflammatory cells (granulomas) in the body and organs. Cellular inflammation can be detected by PET/CT using 18F-fluorodeoxyglucose (18F-FDG), a radio-labeled sugar, or glucose, molecule which can determine sites of abnormal glucose metabolism.

Cardiac 18F-FDG PET is now included as part of the of the mainstream diagnostic algorithm for cardiac sarcoidosis, as well as for monitoring sarcoid response to immunosuppressive therapy. Cardiac 18F-FDG PET is also unique in its ability to identify both inflammation and myocardial scarring caused by sarcoidosis. In fact, new cardiac PET CPT codes 78432 and 78433 were constructed, in part, to facilitate reporting of cardiac PET imaging for patients with known or suspected cardiac sarcoid.

Isolated cardiac sarcoidosis is clinically evident in approximately 20 percent of sarcoidosis patients and has been historically under-diagnosed. The current coverage determination is dramatically limiting Medicare beneficiary access to this important diagnostic tool that could help prevent the roughly 25 percent of deaths from sarcoidosis that arise from cardiac involvement.

As accurately stated in the proposed rule, the decision to use FDG PET for inflammation and infection is multifactorial. And while the diagnostic performance of 18F-FDG PET for identifying cardiac sarcoidosis has been established, additional studies are needed to more clearly define the role of PET in the diagnosis and management of cardiac sarcoidosis. Therefore, as CMS rationalizes in the rule, leaving determinations to local contractor discretion builds in flexibility to tailor coverage decisions to the pertinent facts of a patient's case. Furthermore, by removing the NCD, as proposed, and allowing for coverage to be determined by the MACs, new and ever-expanding clinical applications of PET will not be limited by an NCD for which the scientific literature will likely outgrow within the next decade.

In addition to removing NCD #220.6.16, it appears the Agency will need to make a conforming change to the introductory Preamble in section 220.6 of the Medicare National Coverage Determinations Manuel, which states:

> NOTE: This manual section, 220.6 lists all Medicare-covered uses of PET scans. Except as set forth below in cancer indications listed as "Coverage with Evidence Development," a particular use of PET scans is not covered unless this manual specifically provides that such use is covered. Although this section, 220.6 lists some non-covered uses of PET scans, it does not constitute an exhaustive list of all non-covered uses.

We are concerned that if this language is not modified, the removal of the NCD for FDG PET for Infection/Inflammation will continue to be superseded by the language in the Preamble, which is non-specific to any one particular NCD, and indications that are currently non-covered specifically under that NCD will remain non-covered.

ASNC recommends the following revision to the Preamble of section 220.6 of the Manual:

> ***NOTE: This manual section, 220.6 lists all nationally Medicare-covered uses of PET scans. ~~Except as set forth below in cancer indications listed as "Coverage with Evidence Development," a particular use of PET scans is not covered unless this manual specifically provides that such use is covered. Although this section, 220.6 lists some non-covered uses of PET scans, it does not constitute an exhaustive list of all non- covered uses.~~***
>
> ***~~Effective for dates of service on or after March 7, 2013,~~*** **Notwithstanding any contrary language in this manual, effective for dates of service on or after January 1, 2021, except when there is an applicable NCD,** ***MACs may determine coverage within their respective jurisdictions for positron emission tomography (PET) using radiopharmaceuticals for*** **both** ***their Food and Drug Administration (FDA) approved labeled indications*** **and for their off-label indications supported by adequate clinical data when used for imaging of non-oncologic diseases.** ***~~for oncologic imaging~~.***

These proposed revisions are parallel to, and consistent with, language giving MACs discretion to cover oncologic PET scans. It is particularly important that MACs be given authority to cover off-label indications for radiotracers because FDG and other tracers for non-oncologic imaging, including those for infections and inflammation, are off-label and have become standard care. The above revisions also provide clarity as to MAC discretion in covering PET scans.

MEDICARE APPROPRIATE USE CRITERIA PROGRAM FOR ADVANCED DIAGNOSTIC IMAGING

Although outside this rulemaking, **ASNC commends the Agency for extending the Educational and Operations Testing Period for the AUC Program for advanced diagnostic imaging through CY 2021**, during which there will be no payment consequences associated with the program.

ASNC has previously expressed to the Agency its concerns with the AUC Program, including overlapping intent of the program with existing CMS quality and value-based initiatives, including alternative payment models, the Merit-based Incentive Payment System, and other innovative models, including the Primary Cares Initiative, being tested through the Centers for Medicare and Medicaid Innovation. Not only is the mandated AUC Clinical Decision Support Tool Program outdated and

unnecessary in an environment of evolving payment and delivery models in which providers are at financial risk, the program also diverts provider resources away from quality improvement and unnecessarily contributes to provider administrative burden and practice costs.

Most concerning, however, is the program will take away provider flexibility for consulting AUC. Clinicians are required to only use Clinical Decision Support Mechanisms qualified by CMS. Cardiologists, in institutions that have acquired and implemented a qualified CDSM, are being forced, in many cases, to abandon long-standing methods of AUC consultation, as well as the consultation of specialty-specific AUC, potentially leading to reduced quality of patient care.

ASNC acknowledges CMS does not have the authority to disregard or significantly alter the requirements of the program. However, we ask the Agency to make transparent the continued challenges with program implementation, including documentation of required AUC information on Medicare claims.

ASNC and its members have long promoted the use of AUC for cardiac imaging. As early adopters, we know a stand-alone program is unnecessary to encourage consultation of AUC. For example, from the 1990s to the mid-2000s, nuclear myocardial perfusion imaging was responsible for much of the growth in cardiac imaging until an abrupt decline that began in 2006,[2] which may be explained, in part, by the publication in 2005 of AUC for nuclear cardiac imaging. In fact, much of the consultation of nuclear cardiac imaging AUC has occurred without the use of computer order entry. New payment models will encourage the consultation of AUC. As such, **ASNC does not support further implementation of the AUC Program as currently set forth in statute.**

Practice Expense RVU Updates

Between 2007 and 2008, the Physician Practice Information (PPI) Survey, created by the American Medical Association (AMA), was administered in conjunction with national medical specialty societies and other health care professional groups. The purpose of the survey was to update the practice expense component of Medicare physician payments. The result of the survey was a cut of 36 percent to nuclear cardiology, with equally devastating cuts across other sectors of the cardiovascular community. ASNC and other societies argued at the time the survey contained a limited data set that did not not accurately reflect true practice costs.

As the RAND Corporation continues its CMS-commissioned study to identify potential improvements to CMS' practice expense allocation methodology, we ask that each unique specialty have the opportunity for meaningful input and that ongoing discussions be fully transparent.

Supervision of Diagnostic Tests by Certain Non-physician Providers

With regard to CMS' proposal to allow NPs, CNSs, PAs or CNMs to supervise diagnostic tests on a permanent basis, ASNC believes this modification will allow physicians to use their medical

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[2] McNulty EJ, Hung Y, Almers LM, Go AS, Yeh RW. Population Trends From 2000-2011 in Nuclear Myocardial Perfusion Imaging Use. JAMA. 2014;311(12):1248–1249. doi:10.1001/jama.2014.472

judgement to determine when it is appropriate and safe for non-physician providers to supervise diagnostic tests when they are authorized to do so under state law and scope of practice.

CONCLUSION

ASNC thanks CMS for the opportunity to comment. Questions or requests for additional information should be directed to Camille Bonta at cbonta@summithealthconsulting.com or (202) 320-3658,

Sincerely,

Sharmila Dorbala, MD
President, American Society of Nuclear Cardiology