



September 18, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: File Code CMS-715-P; CY2020 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Policies; (August 14, 2019)

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 CY2020 Revisions to Payment Policies under the Physician Payment Schedule as published in the *Federal Register* on August 14, 2019.

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 specific comments on the items below from the CY2020 Medicare Physician Fee Schedule (PFS) 2020 Proposed rule:

- i. Proposed valuation of Positron Emission Tomography (PET) codes
 - **(51) Myocardial PET (CPT Codes 78459, 78X29, 78491, 78X31, 78492, 78X32, 78X33, 78X34, and 78X35)**

Clinical Utility of Positron Emission Tomography (PET)

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

PET and CT-FFR

ASNC and the American College of Cardiology appreciated the opportunity to meet with CMS representatives on September 3 to discuss proposed payment for cardiac PET. During that meeting, ASNC was asked to comment on CT derived fractional flow reserve (CT-FFR). CT-FFR is a promising emerging technology used as an add-on to coronary computed tomography angiography (CTA) to help determine whether indeterminate coronary lesions are functionally significant. PET Flow also helps determine significance of coronary stenoses. These are two different tests, each with strengths and limitations. At this point, PET Flow (which can be reported with a category I CPT code beginning January 2020) has been shown to be a powerful prognosticator and shows promise in helping to determine which patients will have survival benefit from coronary revascularization. PET studies can be effectively performed in almost all patients, including those with renal failure, very heavy coronary calcifications, prior coronary stents, and contrast allergies and this is an advantage over coronary CTA. PET Flow is valuable in most, but not all patient groups. Coronary CTA and CT FFR are less useful in patients who have established coronary artery disease. Both CT-FFR and PET Flow quantitation are the subject of active ongoing investigation.

Myocardial PET (CPT Codes 78459, 78X29, 78491, 78X31, 78492, 78X32, 78X33, 78X34, and 78X35)

Contractor Pricing and Transition

Currently, nuclear medicine PET codes (78459, 78491, and 78492) have had a professional RVU set by CMS and the technical component has been set by local contractors as “C” contractor-priced. For CY2020, CMS has proposed to accept RUC inputs to set technical and global rates. We support the process of moving from carrier priced codes and establishing RVUs based on RUC and stakeholder invoices. However, ASNC is profoundly concerned that CMS did not accept the RUC inputs and assumptions. Thus, the resulting valuation from CMS does not accurately represent the costs required to perform PET services.

Rather than finalize payment rates as proposed, **ASNC recommends that CMS use the most recent contractor priced claims data (2018) for paid claims for 78459, 78491, 78492 (using the weighted average) in the physician office and independent testing facility setting.** This approach would keep payment rates stable in CY2020 and allow stakeholders the opportunity to provide CMS additional information, in addition to what has already been provided (including

updated invoices provided by the AMA RUC), and review and comment on proposed RVUs with updated inputs for CY2021.

CMS' proposal in the CY2020 rule would result in a technical rate of \$272 and a global rate of \$349 for myocardial PET. This translates to a 72 percent cut when compared to the 2017 actual weighted average paid claims rate of \$1,145. If CMS does not make corrections to inputs requested by ASNC, other stakeholders, and the RUC, there is a significant risk that providing this important technology in the physician practice setting will no longer be financially feasible.

An abrupt move from contractor prices to rates that are significantly below current rates has the potential to be highly disruptive and have a deleterious effect on access and patient care. CMS should use the most current paid contractor claims for 78459, 78491, and 78492 to establish a weighted average technical rate in 2020 while stakeholders review CMS' updated RVUs with updated invoices and corrected utilization.

Finally, as stated in §220 of the "Protecting Access to Medicare Act of 2014" (PAMA) (P.L. 113-93), no service should be reduced by 20 percent or more in one year. It is clear Congress wanted to avoid disruptions to patient access and physician practices when substantial cuts to services occur. The intent of §220 is clear and should be applied to 78459, 78491, 78492. **Thus, CMS should use the final weighted average of \$1,145 for CY 2020, and in the event payment rates for cardiac PET are reduced by 20 percent or more in CY2021, they should be phased-in over at least a period of two years, consistent with §220 of PAMA.**

Practice Expense

CMS proposes a 90 percent utilization rate for PET and PET/CT equipment. CMS gives no explanation for this assumption nor does it refer to data to support it in this proposed rule. ASNC believes a 90 percent utilization rate is unjustifiably high. The Food and Drug Administration (FDA) requires companies that manufacture Rubidium generators to submit data from aspects of delivery of the radiotracer. One of the data points required by the FDA is the number of patients imaged using Rb 82 from their generator (most facilities use one generator). These data show that an average of just 4.5 patients per day are imaged. CMS should receive more specific data in comments from the manufacturers of radiotracers and providers. An assumption of 50 percent utilization would be a more accurate assumption of actual use of a PET or PET/CT camera in the office setting. The physician office is unlike a hospital setting where PET or PET/CT procedures with largely similar resources might be shared between cardiology and oncology and utilized during hours that fall outside the normal business hours of a physician practice. **ASNC urges CMS to use the 50 percent utilization rate on both PET and PET/CT cameras.**

ASNC members have shared detailed accounting of infrastructure costs associated with installation and maintenance of PET machines. Required items include lead lining pursuant to regulations from the Nuclear Regulatory Commission or state authorities in non-agreement states, specialized separate cooling systems for PET machines, and machinery to place the PET cameras in a building. These costs can quickly add hundreds of thousands of dollars to required costs of providing myocardial PET and payment rates that do not account for these costs further disadvantage labs providing PET.

Additionally, CMS argues that it should not add in the cost of “software and hardware packages for Absolute Quantitation” as a new equipment item because the invoices that were submitted included a service contract with a combined software/ hardware bundle and the items were not broken into individual costs. Based on the absence of pricing data for the individual items, CMS believes the costs of the items are indirect PE inputs that would not be allocable to the individual patient for a PET service.

ASNC strongly disagrees with the characterization of the software and hardware packages as indirect costs. Nuclear medicine hardware must have software to run them or they don’t work, and the same is true of CT and MRI hardware. For the clinician to analyze blood flow there must be both hardware and software to run it. **ASNC urges CMS to price hardware and software packages for absolute quantitation which is in line with the recommendation from the RUC.**

Physician Work

In 2016, 78492 (*Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fraction(s), when performed); single study, at rest or stress (exercise or pharmacologic)*) was selected in a high-growth screen. The AMA RUC committee then referred the code to the CPT Editorial panel given the need to revise and update the descriptors due to technological advances in PET including wall motion, ejection fraction, software/ hardware updates, and the development of PET absolute quantitation of myocardial blood flow. The CPT panel approved revision of the three existing PET codes (78491, 78492, 78459) and the addition of six Category I codes. The CPT also approved the deletion of an existing Category III code for Absolute Quantitation of Myocardial blood flow and the new Category I code for Absolute Quantitation of Myocardial blood flow. The updates of existing codes and addition of six Category I codes encapsulate important changes in instrumentation, computer processing, and software that allow for extraction of greater clinically valuable information on metabolism, perfusion, and function.

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommended work RVU
78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed) single study;	1.25*	1.61

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommende d work RVU
78X29	Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed) single study; with concurrently acquired computed tomography transmission scan	1.40*	1.76
78491	Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); single study, at rest or stress (exercise or pharmacologic)	1.00	1.56
78X31	Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fraction(s), when performed); single study, at rest or stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	1.11	1.67
78492	Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fraction(s), when performed); multiple studies at rest and stress (exercise or pharmacologic)	1.74*	1.80
78X32	Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fraction(s), when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	1.84*	1.90

Code	Long Descriptor	CMS Proposed work RVU	RUC Recommende d work RVU
78X33	Myocardial imaging, positron emission tomography, combined perfusion with metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed), dual radiotracer (eg, myocardial viability);	1.71*	2.07
78X34	Myocardial imaging, positron emission tomography, combined perfusion with metabolic evaluation study (including ventricular wall motion(s), and/or ejection fraction(s), when performed), dual radiotracer (eg, myocardial viability); with concurrently acquired computed tomography transmission scan	1.90*	2.26
78X35	Absolute quantitation of myocardial blood flow (AQMBF), positron emission tomography, rest and pharmacologic stress (List separately in addition to code for primary procedure)	0.42	0.63

**Different work RVUs indicated in Table 20 and Addendum B versus the text of the Proposed Rule*

CMS proposes a decrease in the work RVUs for all the Myocardial PET codes. **CMS' proposal takes no account of the fact that the physician work involved with these services has changed.** There have been substantial changes in instrumentation, hardware and software since the 1990s, and the technology to perform wall motion and ejection fraction did not even exist when PET codes were first developed. These advances have enhanced acquisition, processing, quality control, and interpretation and have consequently added new variables for physician analysis. The advances in PET perfusion imaging have had a marked impact on patients with advanced and complex heart failure, valvular heart disease, and suspected myocardial inflammation.

In addition, CMS does not account for the work done by several pre-facilitation committees at the RUC. Those committees were given data on the unreliability of the time estimates from the very old prior survey which had a low number of respondents from a low number of sites

performing cardiac PET in those early days of the technology

Total Time Ratio and Valuing the Increment

CMS uses an invalid methodology for a total time ratio to develop a work RVU for 78491- Myocardial imaging, positron emission tomography, perfusion study (including ventricular wall motion(s), and/or ejection fractions(s), when performed); single study, at rest or stress (exercise or pharmacologic). Thus, the entire proposal for the family of services is flawed because the family of codes are built off proposed values for 78491. ASNC asks that CMS not treat all components of physician time as having identical intensity and use established methods of formulation of RBRVS (such as magnitude estimation, survey data, and clinical expertise) to evaluate physician time. Applying varying intensities to only certain services creates payment differentials in a system that is dependent on relative valuation. CMS does not seem to be using one methodology and is using a number of different inputs from a number of different methodologies to arrive at physician work.

ASNC echoes the RUC in asking that CMS refrain from valuing the increment and treating all components of physician time as having identical intensity. ASNC asks that CMS look to clinical information justifying changes in physician work intensity that the RUC provides.

78459 PET Metabolic – Single Study

CMS does not follow the RUC recommendation to increase the work RVU to 1.61 and instead proposes a physician work RVU of 1.25. CMS arrives at this proposal by applying the increment between 78459 and the myocardial PET perfusion code 78491. The methodology for developing the valuation of the increment is unclear and varies from .05 to .25. CMS provides no direct crosswalks and does not provide clinical rationale for a lower work RVU.

The proposed work RVU of 1.25 is a gross underestimate of the physician work that is performed to provide this service. The survey data gave a 25th percentile work RVU of 1.61 and is an appropriate accounting of the work required to perform 78459. 78459 describes a PET scan that evaluates metabolism with a tracer such as a glucose analog rather than a PET scan that evaluates myocardial blood flow. The RUC recommends that 78459 requires slightly more in the way of physician work than 78491- PET, single study (recommended RVU=1.56) because of the challenging nature of analyzing glucose analog uptake into the myocardium. Because the heart's primary energy source is fatty acid and not glucose (like brain and skeletal muscle) the physician has to assure that certain metabolic conditions are met at the time of injection and patients must have followed a specific diet prior to the scan.

ASNC asks that CMS use valid survey data from physician who perform this service and use a work RVU of 1.61 for 78459.

78X29 PET Metabolic – Single Study with CT

CMS does not follow the RUC recommendation to set the work RVU at 1.71 for this code and instead proposed a physician work RVU of 1.40. Again, CMS arrives at this recommendation by

applying the increment between 78X29 and myocardial PET perfusion code 78491. The methodology for developing the valuation of the increment is unclear and varies from .20 to .40.

The proposed work RVU of 1.40 is a gross underestimate of the physician work that is performed to provide this service. The survey data gave a 25th percentile work RVU of 1.76 and is an appropriate accounting of the work required to perform 78X29. The RUC agreed that 78X29, which includes a CT, requires three more minutes of intra-service time and two more minutes immediate post-service time than myocardial PET without CT (78459).

ASNC asks that CMS use valid survey data from physicians who perform this service and use a work RVU of 1.71 for 78X29.

78491 PET Perfusion – Single Study

CMS does not follow the RUC recommendation to increase the work RVU of 1.56 for this service and instead proposed a physician work RVU of 1.00. CMS ignores the recommended change in physician work and asserts that because there is a reduction in service time the recommended value must be overstated. CMS references 78278- acute gastrointestinal blood loss imaging and (work RVU-.99) and fine needle aspiration biopsy, without imaging guidance; first lesion (work RVU-1.03).

The total time ratio is not a valid method to value this service. This methodology corrupts the rest of the proposed values in this code family as 78491 is used as a base of the code family. A work RVU of 1.00 is a gross underestimate of the physician work required to perform this service. The survey data gave a 25th percentile work RVU of 1.56 and is an appropriate valuation of the work required to perform 78491.

78491 requires much more work than the codes CMS uses as references in its proposal. CMS referenced 78278-(acute GI bleeding scan) and 10021-(fine needle aspiration biopsy, without imaging guidance; first lesion) as comparators. Both of these codes have no 3D component and require no manipulation and there are no analytics or additional organs to analysis during the study.

ASNC asks that CMS use valid survey data from physicians who perform this service and use a work RVU of 1.56 for 78491.

78X31 PET Perfusion – Single Study with CT

CMS does not follow the RUC recommendation to set the work at an RVU of 1.67 and instead proposes a work RVU of 1.11. CMS argues the proposed value is between 95977- *Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*) and 93284-

Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system.

Again, CMS uses the flawed methodology and applies an increment that has no direct crosswalks and is not informed by clinical inputs that results in a lower work RVU. A work RVU of 1.11 is a gross underestimation of the physician work required to perform this service. The RUC recommendation of 1.67 is an appropriate estimation of the physician work required to perform this service.

78X31 requires more work than the comparator codes referenced by the RUC. 78814 (*PET with concurrently acquired CT for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)*) has a work RVU of 2.20 and a total time of 60 minutes and requires slightly less physician time than 78X31. 78072 –(*parathyroid planar imaging (including subtraction, when performed); with tomographic SPECT and concurrently acquired computed tomography CT for anatomical localization*) was an additional RUC comparator with a work RVU of 1.60 and a total time of 30 minutes. 78X31 is more complex and intense to perform than 78072.

In addition, CPT code 78X31 requires much more work than the two services that CMS uses as comparators-95977- (*electronic analysis of implanted neurostimulator pulse generator/transmitter*) and 93284- (*programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis review and report*). 78X31 requires the selection of a radiopharmaceutical with distribution and anatomy involving many images through slice and cine review. Moreover, the physician is required to review data on ejection fraction, wall motion in many patients and clinical symptoms for each patient. The CMS comparators are not appropriate and do not have any element of perfusion and computation that other nuclear medicine services would contain. Comparators such as 78072 – SPECT/ CT parathyroid have some of the CT and 3D elements and only the additional complexity of PET would need consideration.

ASNC asks that CMS use valid survey data from physicians who perform this service and use a work RVU of 1.67 for 78491.

78492 PET Perfusion – Multiple Studies

CMS does not follow the RUC recommendation of an RVU of 1.80 and proposes a work RVU of 1.74 for 78492. CMS arrives at the proposed RVU by applying the increment between 78491 and 78492. It is unclear how CMS arrives at this increment given in increments vary from .13 to .63. CMS again applies an invalid method without crosswalks or clinical input to support their proposal.

We are not sure why CMS proposes a value only .06 RVUs lower than those supported by the RUC value. The work RVU of 1.80 is an appropriate estimate of the work required to perform 78X32.

ASNC asks that CMS use valid survey data from physicians who perform this service and use a work RVU of 1.80 for 78492.

78X32 PET Perfusion – Multiple Studies with CT

CMS does not follow the RUC recommendation of an RVU of 1.90 and proposes a work RVU of 1.84 for 78X32. CMS bases its recommended value on the increment between single study perfusion PET -78491 and myocardial perfusion PET, multiple studies with CT, 78X32. It is unclear why this increment is used given that CMS uses the increment between the *single* study PET and the *multiple* study PET with CT. CMS continues to apply a flawed method with no direct crosswalks and without clinical input.

We are confused why CMS disregards a valid crosswalk to offer an RVU .06 lower than the RUC recommendation. The RUC recommendation of 1.90 is an appropriate value of the work and time required to perform 78X32.

RUC compares this service to 75574 *Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)* which has a work RVU of 2.40 and a total time of 50 minutes and 78814 *Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)* which has a work RVU of 2.20 and a total time of 60 minutes. The RUC noted that 78X32 requires less physician work and time to perform and, thus, 78x32 is appropriately valued.

ASNC asks that CMS use valid survey data from physicians who perform this service and use a work RVU of 1.90 for 78X32.

78X33 PET Perfusion Single Study + Metabolic Study

CMS does not follow the RUC recommendation of an RVU of 2.07 and proposes a work RVU of 1.71 for 78X33. CMS applies an incremental methodology using the RUC increment between 78491 and 78X33. It is not clear how the increment is developed given that it varies from .51 to .71. Again, CMS uses the *single* study PET and metabolic codes to compare to 78X33 which is a PET perfusion *multiple study with CT*.

The proposed work RVU of 1.71 is a gross underestimation of the physician work required to perform this service. The RVU of 2.07 recommended by the RUC is an appropriate valuation of the work required to perform this service. 78X33 includes PET perfusion and metabolic studies and is an intense service performed on complicated patient with ejection fractions less than 30 percent and multi vessel coronary disease. The physician is trying to determine if there is enough

viable tissue to make revascularization worthwhile. The physician inspects myocardial perfusion and myocardial metabolism, searching for regions that have mismatch which are therefore threatened but viable.

ASNC asks the CMS use valid survey data from physicians who perform this service and use a work RVU of 2.07 for 78X33.

78X34 PET Perfusion Single Study + Metabolic Study with CT

CMS does not follow the RUC recommendation of work RVUs of 2.26 and proposed a work RVU of 1.90 for 78X34. CMS applies the increment between the PET perfusion single study code 78491 and Myocardial PET perfusion single study and metabolic study with CT code with 78X34. It is not clear how CMS arrives at the increment since it varies from .50 to .70. There is a question as to why CMS uses the *PET single study* code to compare to a *PET perfusion single study and metabolic multiple study with CT*.

CMS' method of applying increments with no direct crosswalks and no clinical input to arrive at a lower RVU is not valid. The RUC recommendation of 2.26 is an accurate valuation of the physician work required to perform this service.

The RUC compared 78X34 to 75561 *Cardiac magnetic resonance imaging for morphology and function without contrast material(s), followed by contrast material(s) and further sequences*; which has a work RVU of 2.60 and a total time of 65 minutes. The RUC also compared 78815 *Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh* which has a work RVU of 2.44 and a total time of 65 minutes and noted that CPT code 78X34 requires less total physician work and time to perform.

ASNC asks that CMS use valid survey data from physicians who perform this service and use a work RVU of 2.26 for 78X34.

78X35

CMS does not follow the RUC recommendation of .63 RVU and proposes .42 for 78X35. CMS based valuation for other codes in this family on their relative relationship to PET perfusion single study 78491 and for that code the agency analysis indicates that a reduction of one-third of the RUC-recommended value is appropriate. Thus, they applied a reduction of one-third from the RUC-recommended value of .63 to arrive at a proposed value of .62. This methodology is flawed and a work value of .63 is appropriate. This service involves complex computation and is performed in real-time. There are a variety of regions of interest to review and a variety of curves to match for differences between rest and stress and the physician must attempt to adjudicate those values in three different vascular beds. This is not simply the reporting of a number nor physician validation of a computer-generated number.

ASNC asks that CMS use valid survey data from physician who perform this service and use a work RVU of .63 for 78X35.

Conclusion

ASNC thanks CMS for the opportunity to comment and would welcome any questions or requests for additional information. Please contact Georgia Lawrence, Director, ASNC Regulatory Affairs, at glawrence@asnc.org with any questions.

Sincerely,

A handwritten signature in black ink that reads "Rob Beanlands". The signature is written in a cursive style with a large, sweeping flourish at the end.

Rob Beanlands, MD
President,
American Society of Nuclear Cardiology