

September 13, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20001

Re: File Code CMS 1751- P. Medicare Program; CY2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates: Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-LaSure:

On behalf of the American Society of Nuclear Cardiology (ASNC), I appreciate the opportunity to provide comment on the CY 2022 Medicare Physician Fee Schedule (PFS) proposed rule, published in the *Federal Register* on July 23, 2021 (86 Fed. Reg. 39104).

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 with the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology and cardiovascular computed tomography.

ASNC offers comment on the following:

- CY2022 Conversion Factor
- Clinical Labor Pricing Updates
- Proposed Retirement of Section 220.6 of the NCD Regarding PET Imaging
- Comment Solicitation for Fraction Flow Reserve Derived from Computed Tomography
- Medicare Appropriate Use Criteria Program

CY 2022 CONVERSION FACTOR

For CY2022, CMS proposes a conversion factor of 33.5848 which reflects the budget neutrality adjustment under 1848(c)(2)(B)(ii)(II) of the Act, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the expiration of the 3.75 percent increase for services furnished in CY2021 as provided by the 2021 Consolidated Appropriations Act.

ASNC calls on CMS to urge Congress to provide a positive update to the Medicare conversion factor in 2022 and all future years.

Updates to the conversion factor have failed to keep pace with inflation and the result is that today's conversion factor is only 50 percent of what it would have been if it had been indexed to general inflation starting in 1998. Providers are consistently asked to adapt to the costs of running a medical practice even as reimbursement is unpredictable and can be subject to significant reductions from year to year.

CLINICAL LABOR PRICING UPDATES

In the CY2022 PFS proposed rule, CMS proposes updates of clinical labor pricing using the 2019 United States Bureau of Labor Statistics wage data. The proposed updates in clinical labor pricing result in a 12 percent cut in reimbursement to 78452 – *Myocardial Perfusion Imaging, Tomographic (SPECT)(Including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); Multiple studies, at rest and/ or stress (exercise or pharmacologic) and/ or redistribution and/ or rest reinjection*. SPECT is performed to diagnose suspected coronary artery disease by detecting areas of the heart that have inadequate blood flow as compared to areas that have normal flow.

The CY2022 proposed clinical labor pricing update would change the rate per minute for a nuclear medicine technologist from the current rate of .62 to .88, a 43 percent increase. The effects of this increase on specialty payment depend on the share that labor costs represent of the practice expense inputs for each specialty. Because nuclear cardiology has a lower share of direct costs associated with clinical labor and has high-cost supplies, the result is significant decreases in payment due to this proposed clinical labor update and subsequent budget neutrality adjustment.

Put simply, the cut that some nuclear cardiology services will sustain as a result of budget neutrality is unfair. The wages paid to technologists are going up, as are the costs of machines and equipment; yet, CMS is proposing a cut to services, that should otherwise be experiencing a payment increase, to preserve budget neutrality. At a minimum, the real cost of providing these and other services should be recognized with a positive payment update to the Medicare conversion factor in 2022 and beyond.

This significant downward shift in reimbursement, as proposed, would occur within an environment of uncertainty in which the lingering COVID-19 public health emergency has led to widespread and significant health care staffing shortages, increased costs and decreased productivity stemming from new COVID protocols, and other burdens on already stressed clinical resources. There should be a thoughtful approach by CMS and Congress to address the problem of physician fee schedule budget neutrality. **ASNC asks CMS to defer until after 2022 the use of the proposed clinical labor pricing updates, and, in absence of a solution to budget neutrality, updates to clinical labor pricing should occur over a four-year transition period.** In addition, ASNC urges CMS to update pricing data for clinical labor costs and equipment more frequently to avoid sudden and drastic shifts in reimbursement.

PROPOSED RETIREMENT OF SECTION 220.6 OF THE NCD REGARDING PET IMAGING

In the proposed rule, CMS asks stakeholders for feedback on its proposal to retire section 220.6 of the National Coverage Determinations (NCD) Manual on positron emission tomography (PET) scans. Specifically, section 220.6 of the NCD Manual states that in general, “a particular use of PET scans is not covered unless this manual specifically provides that such use is covered.” If CMS finalizes its proposal of section 220.6, it will “allow local Medicare contractors to make a coverage determination[s] under section 1862(a)(1)(A) of the Act for beneficiaries” with respect to non-oncologic PET imaging. Importantly, CMS is clear in the proposed rule that no changes will be made to any of the subsections of section 220.6.

ASNC supports CMS’ proposal to retire section 220.6 of the NCD Manual on PET scans. We are aware that new PET imaging agents are under development, and, in the absence of this retirement, those agents would have to go through a rigorous, time-consuming reconsideration process. If finalized, this policy would allow MACs to make local coverage determinations allowing an immediate pathway to potential coverage.

While we are supportive of the retirement of section 220.6 and are confident that CMS’ proposal is meant to leave existing coverage in place, we want to be explicit in our view that coverage for PET for Perfusion of the Heart (220.6.1) and FDG PET for Myocardial Viability (220.6.8) should not be altered. PET scans for perfusion of the heart provide strong prognostic value for the assessment of coronary artery disease. PET offers accuracy of diagnosing coronary artery disease and identifying high-risk patients that is superior to other techniques. Furthermore, PET allows physicians to measure the function of the heart’s microvasculature. No other test noninvasively assesses microvascular disease which can cause angina and increase the risk of heart attack when dysfunctional.

COMMENT SOLICITATION FOR FRACTION FLOW RESERVE DERIVED FROM COMPUTED TOMOGRAPHY

In the CY2022 proposed rule, CMS asks stakeholders for feedback on methods of valuing artificial intelligence (AI) technologies given the recent development of a code set of category III FFRCT codes. ASNC is pleased that CMS is analyzing methods of valuation of AI and other innovative technologies. We agree that many of the resources required for the provision of these services are not well accounted for in current practice expense methodologies. While not widespread, AI is increasingly being applied to services in nuclear cardiology and is used to improve image segmentation, disease diagnosis, and risk prediction. In nuclear cardiology, AI is used to automate processes that would normally require tedious manual adjustments, and in risk prediction, AI can objectively integrate multiple potential parameters or directly predict the outcomes of interest from images and explain the predictions. We look forward to working with CMS in future years on valuing AI as it evolves and is applied in the field of nuclear cardiology.

MEDICARE APPROPRIATE USE CRITERIA PROGRAM

Revisit and Repeal

It is the position of ASNC and numerous other medical societies that the AUC Program should be abandoned and that CMS should work with stakeholders to identify other mechanisms to encourage the consultation of AUC. We have been frustrated by the apparent lack of communication between CMS and Congress about the implementation challenges associated with the program. But, more significantly, we are disappointed with the absence of a dialogue about how existing Medicare quality programs can be leveraged to encourage the consultation of AUC in a manner that is flexible and targeted.

ASNC is encouraged by the language included in the House-passed Fiscal Year 2022 Labor-Health and Human Services-Education spending bill that requests a report from CMS on the implementation of the AUC Program, which we hope will lead to legislation that repeals or, at a minimum, substantially modifies the AUC Program. The House report language reads as follows:

Medicare Appropriate Use Criteria Program — The Committee is aware that the Protecting Access to Medicare Act established the Medicare Appropriate Use Criteria (AUC) Program for advanced diagnostic imaging. While the Committee recognizes the value of encouraging physicians and other health care professionals to consult AUC and clinical guidelines to support medical decision making, more than seven years have passed since Congress created the AUC program, which has not advanced beyond educational and operations testing. The Committee requests a report within 180 days of enactment of this Act on implementation of this program, including challenges and successes. In this report, CMS shall consider existing quality improvement programs and relevant models authorized under Sec.1115A of the Social Security Act and their influence on encouraging appropriate use of advanced diagnostic imaging. The Committee directs CMS to consult with stakeholders, including medical professional societies and developers of AUC and clinical guidelines, when formulating its report.

We ask that CMS work expeditiously and in consultation with ASNC and other medical societies to fulfill the congressional request once the spending bill is finalized. We further ask that the report provide a comprehensive examination of existing and emerging quality improvement programs, as well as relevant models being pursued by the Centers for Medicare and Medicaid Innovation, and how they can influence appropriate use of advanced diagnostic imaging.

AUC Program Delay of Payment Penalty Phase

ASNC fully supports CMS' proposal to delay the payment penalty phase of the AUC program until the later of Jan. 1, 2023, or the January 1 that follows the declared end of the public health emergency (PHE) for COVID-19. Throughout the pandemic, physician practices have struggled with staffing shortages, which have resulted in assigning staff to only essential responsibilities with little-to-no excess capacity for added administrative tasks, including preparing for a possible eventuality of full AUC program implementation. In fact, we

have heard from ASNC physician members who are reluctant to make administrative and staff investments in the AUC program, as well as to acquire and integrate a CMS qualified clinical decision support mechanism (CDSM) amidst the uncertainty of the program's future following the more than seven years since the 2014 enactment of the *Protecting Access to Medicare Act* which established the program.

As ASNC has previously commented, entities that have implemented CDSMs in large systems have recommended a period of at least 12 – 18 months between publication of a final rule and the effective date for consultation and reporting requirements. Data use contracts must be negotiated and reviewed; physicians, coders, and billing departments must be trained; and provider workflows need to adjust. **Given the lingering uncertainty regarding establishing necessary edits in the claims processing system, physicians must be given at least 12 months to prepare for the penalty phase of the program once CMS makes public that all claims processing edits have been made and tested successfully.**

We recognize CMS is attempting to fulfill its statutory obligations to implement the AUC Program. We further recognize the prescriptive nature of the law offers the Agency little flexibility with program implementation, and that the complexity and vastness of the law are compounded by the lack of a historical model in Medicare for the exchange of information between providers and the documentation requirements using Medicare claims.

In response to the question posed in the proposed rule of whether the payment penalty phase of the program should begin first with returning claims and then transition to denying claims after a period of time, **we urge CMS not to advance implementation with the payment penalty phase until the Agency has determined the overwhelming number of claims will not be rejected or denied due to AUC reporting errors or claims processing issues.**

In the rule, CMS presents scenarios as being potentially challenging or impracticable for application of the AUC program claims processing edits for purposes of the payment penalty phase. While we appreciate CMS' efforts in this respect, the need to create workable solutions to ensure only appropriate claims are subject to the AUC claims processing edits serves to underscore the complexity of the program.

Leveraging Existing Medicare Quality Programs

With 99.99 percent of eligible clinicians having participated in MIPS in 2019, the opportunity exists to utilize MIPS as a platform for encouraging the consultation of AUC. In the seven years since enactment of PAMA, opportunities have been lost to significantly advance clinically appropriate ordering of AUC through physician education and by leveraging other Medicare quality improvement programs and innovative payment models

CMS could build upon MIPS appropriate use measures and improve upon the current high-weighted Improvement Activity "*Consulting AUC Using Clinical Decision Support when Ordering Advanced Imaging*" by allowing physicians and other health care professionals to consult AUC using a mechanism that is best-suited for their practice and specialty. We suggest there is also opportunity for targeted efforts to encourage the consultation of AUC. For example,

according to CMS, among the 10 specialties with the most participants in the MIPS program are primary care, emergency medicine, diagnostic radiology, cardiology, orthopedic surgery, and general surgery. CMS states it is important to develop MIPS Value Pathways (MVPs) that address these specialties, and as specialties that all rely in some manner on diagnostic imaging, there is tremendous opportunity to use these MVPs to encourage, with greater precision and flexibility, clinically appropriate use of all imaging services, not just advanced diagnostic imaging.

ASNC has previously commented to CMS that high-volume imaging services are not necessarily correlated with high rates of inappropriate testing. However, the AUC Program is sweeping and undiscerning. For example, CMS has chosen to focus on chest pain (angina, suspected myocardial infarction, and suspected pulmonary embolism) as a clinical priority area largely on the basis of volume. However, in the majority of chest pain cases, providing an advanced imaging test to a symptomatic patient in the Medicare population would be an appropriate test.

A 2011 study of AUC for single-photon emission computed tomography (SPECT) found that the most appropriate SPECT was observed in patients with known coronary disease (72 percent) and chest pain syndrome (89 percent). When comparing symptoms versus asymptomatic, most inappropriate/rarely appropriate and uncertain SPECT was observed in asymptomatic patients.¹

A 2009 study found that more than 90 percent of inappropriate / rarely appropriate cardiac imaging came from just five indications, including: 1) detection of coronary artery disease in asymptomatic low-risk patients; 2) asymptomatic patients less than two years after percutaneous coronary intervention; 3) evaluation of chest pain, low probability interpretable ECG and able to exercise, asymptomatic/stable symptoms; 4) known coronary artery disease less than one year after catheterization or abnormal prior SPECT; and 5) and pre-operative assessment for low-risk surgery.²

These findings were confirmed in a published analysis of 22 studies (that included 23,443 patients) that looked at appropriateness of nuclear myocardial perfusion imaging (MPI) identified the most common reasons for inappropriate /rarely appropriate testing.³

The AUC Program requirements apply to the ordering of all advance diagnostic tests, with exceptions for tests ordered in the emergency department and hospital inpatient.

The AUC program is designed in such a manner that it assumes every physician is starting from ground zero with regard to their understanding and use of AUC. Requiring physicians to click through a CDSM at every order is overly burdensome and unnecessary. Instead, there needs to be a focus and emphasis on “red flag” inappropriate / rarely appropriate ordering — indications for which rarely appropriate ordering remains highly prevalent. For many clinical scenarios, like

¹ Regina S. Druz, Lawrence M. Phillips, and Gulu Sharifova, “Clinical Evaluation of the Appropriateness Use Criteria for Single-Photon Emission-Computed Tomography: Differences by Patient Population, Physician Specialty, and Patient Outcomes,” *ISRN Cardiology*, vol. 2011, Article ID 798318, 8 pages, 2011. doi:10.5402/2011/798318

² Hendel RC, Cerqueira M, Douglas PS, Caruth KC, Allen JM, Jensen NC, et al. A Multicenter Assessment of the use of Single-use Photon Emission Computed Tomography Myocardial Perfusion Imaging with Appropriateness Criteria. *J Am Coll Cardiol*. 2010 Jan 12;55(2):156-62. doi: 10.1016/j.jacc.2009.11.004.

³ Elgendy I, Mahmoud A, Shuster J, Doukky R, Winchester D. Outcomes after inappropriate nuclear myocardial perfusion imaging: A meta-analysis. *J. Nucl. Cardiol*. (2016) 23:680-689 DOI 10.1007/s12350-015-0240-2

chest pain as described above, consultation of AUC will infrequently yield a rarely appropriate response. Instead, **the policy focus should be on educating ordering professionals about the use of AUC in areas where there is greater clinical uncertainty and greater likelihood of clinically rarely appropriate ordering.**

For MIPS eligible clinicians who participate in alternative payment models (APMs), the law also takes away the flexibility of clinicians to use the tools of their choosing to ensure clinically appropriate ordering of advanced diagnostic imaging tests. Because APM participants are at greater financial risk for inappropriate resource utilization, the decision on how to approach the delivery of appropriate tests and services should be left to the APM entity and its participants. Participants in capitated payment models are likewise incentivized to consult AUC and clinical guidelines and to utilize other tools that help them avoid the delivery of low-value care.

While there may be differing ideas about how to foster the use of AUC by clinicians, there is agreement among many in the physician community that the program should be revisited and either repealed or substantially modified on the basis that the program: diverts provider resources away from quality improvement activities; takes away provider flexibility for consulting AUC; adds administrative burden; and is a costly and disproportionate response to imaging utilization.

We hope a dialogue between CMS and Congress, in consultation with ASNC and other AUC stakeholders, will take place pursuant to the House report language and lead to legislative action next year on repeal or modification of the AUC Program.

Clinical Considerations

ASNC strongly supports the development and use of AUC and has been a leader in this regard. When AUC is effectively applied, patients get the right test first. Unfortunately, many ASNC members who provide care in hospital and health systems that were early adopters of a qualified CDSM have found their ability to consult the American College of Cardiology Foundation (ACCF) AUC for nuclear studies has either been taken away from them or extra steps are necessary to access the ACCF AUC in the CDSM. Nuclear cardiologists have been using the ACC AUC since its publication in 2009 and should not be restricted from consulting the ACC AUC because their institution's CDSM makes it impossible or difficult to do so.

As we have previously written to CMS, both the ACCF and the American College of Radiology (ACR) have AUC that address cardiovascular imaging. Substantial methodological differences exist between each organization's approach to AUC. The ACCF AUC place a greater reliance of risk stratification based on clinical factors, which results in a far greater specificity of clinical indications.⁴ A 2016 published study found significant discordance between the ACCF and ACR AUC for nuclear myocardial perfusion imaging.⁵ In this cohort study, 52.2 percent of 67 ACC AUC ratings and 18.8 percent of 592 patients could not be matched to an ACR rating.⁶ The

⁴ Hendel RC. Widespread Implementation of Appropriate Use Criteria for Cardiac Imaging—Which Are Appropriate? JAMA Cardiol. 2016;1(2):211-212. doi:10.1001/jamacardio.2016.0052.

⁵ Winchester DE, Wolinsky D, Beyth RJ, Shaw LJ. Discordance Between Appropriate Use Criteria for Nuclear Myocardial Perfusion Imaging From Different Specialty Societies: A Potential Concern for Health Policy. JAMA Cardiol. 2016;1(2):207-210. doi:10.1001/jamacardio.2016.0030.

⁶ Ibid.

study found far more abnormal imaging studies or individuals with ischemia with a rarely

Table 2. Ischemia and Nuclear MPI Results Stratified by ACR Appropriateness Categories^a

Variable	ACR, No./Total (%)			P Value
	"Usually Appropriate"	"May Be Appropriate"	"Usually Not Appropriate"	
Ischemia SDS >3	52/308 (16.9)	3/57 (5.3)	14/80 (17.5)	.07
Abnormal nuclear MPI	91/324 (28.1)	7/62 (11.3)	29/82 (35.4)	.004

Abbreviations: ACR, American College of Radiology; MPI, myocardial perfusion imaging; SDS, summed difference score.

^a The prevalence of abnormal nuclear MPI differed across the appropriateness categories ($P = .004$), while the prevalence of ischemia (defined as SDS >3) did not ($P = .07$).

appropriate designation from the ACR than with the ACC AUC.

Another study examining the ACCF and ACR AUC for the appropriateness of MPI found the two systems for rating the appropriateness of MPI have poor agreement between them.⁷ The ACR AUC have notably fewer clinical scenarios where the appropriateness of MPI is rated, leaving many specific indications for imaging without an appropriateness rating.⁸ The discordance between the two AUC can create disagreement between payors and providers, which is pertinent when consultation is tied to payment or performance.

AUC Education

Table 3. Ischemia and Nuclear MPI Results Stratified by ACCF Appropriateness Categories^a

Variable	ACCF, No./Total (%)			P Value
	"Appropriate"	"Uncertain"	"Inappropriate"	
Ischemia SDS >3	57/358 (15.9)	11/48 (22.9)	1/39 (2.6)	.03
Abnormal nuclear MPI	104/378 (27.5)	20/49 (40.8)	3/41 (7.3)	.002

Abbreviations: ACCF, American College of Cardiology Foundation; MPI, myocardial perfusion imaging; SDS, summed difference score.

^a The prevalence of abnormal nuclear MPI and the prevalence of ischemia (defined as SDS >3) differed across the appropriateness categories ($P = .002$ and $P = .03$, respectively).

The AUC program requirements for those physicians who have been exposed to consultation through a CMS-qualified CDSM has resulted in pointless clicks to get to the desired result. ASNC firmly believes there needs to be widespread education among ordering clinicians about AUC on a condition-by-condition basis; otherwise, consultation of AUC is meaningless — put bluntly, garbage in is garbage out. We know that education about appropriate use is not effective at the point of order. Where ASNC has witnessed a difference in correcting low-value ordering patterns is direct communication between ordering and rendering clinicians.

As ASNC has previously shared with the Agency, in 2014, ASNC commissioned a behavioral and performance needs assessment of inter-professional referrals and collaboration in nuclear imaging. The needs assessment found that referrers are challenged to apply AUC when selecting

⁷ Bagrova A, Alsamarah A, Winchester D. Comparing two methods for determining appropriateness of myocardial perfusion imaging: Criteria from the American College of Cardiology Foundation and the American College of Radiology. J. Nucl. Cardiol. DOI 10.1007/s12350-017-0965-1

⁸ Ibid.

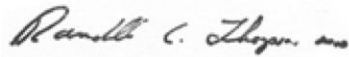
patients for nuclear imaging. ASNC and its partners have undertaken extensive educational efforts directed at primary care physicians on how to consult and correctly apply AUC for advanced imaging tests. In 2015, ASNC offered a satellite symposium at its annual meeting titled, "Appropriate Use of Cardiovascular Imaging for the Referring Clinician." Additionally, in May 2016 ASNC hosted a session at the American College of Physicians annual meeting. These programs were specifically designed for referring providers to allow them to gain competence in utilizing AUC when ordering cardiac imaging procedures. The response from the referring community was very positive and desirous of the education.

The AUC Program, as designed, does not foster the type of education about AUC that is necessary for AUC to have its intended effect.

CONCLUSION

ASNC is pleased to provide comment on the CY2022 Medicare Physician Fee Schedule Proposed rule and would welcome any questions or requests for additional information. Please contact Georgia Lawrence, Director, Regulatory Affairs at glawrence@asnc.org with any additional questions.

Sincerely,

A handwritten signature in dark ink, reading "Randall C. Thompson, MD". The signature is written in a cursive style.

Randall Thompson, MD
President,
American Society of Nuclear Cardiology

