January 27, 2025

Mr. Jeff Wu
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via regulations.gov

Dear Acting Administrator Wu:

The American Society of Nuclear Cardiology (ASNC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') proposed rule, Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage (MA) Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly [CMS-4208-P].

Specifically, ASNC offers comment on the following sections of the rule:

- Improving Access – Enhancing Rules on Internal Coverage Criteria

- Ensuring Equitable Access – Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures

The cornerstone of the patient-physician relationship is based on shared decision-making; that is, to make the decision for the right test or treatment at the right time based on sound clinical judgement and honest discussions with patients about risks and benefits. Prior authorization policies that deviate from Medicare coverage criteria ignore current evidence and disregard the value of shared decision-making, are disruptive to patient care and add burden to clinicians who spend countless hours every week appealing to payers to cover prescribed tests and treatments.

Heart disease is the leading cause of death for men and women in the United States. There are many tests that can be used to diagnose cardiovascular diseases and conditions. Which test is ordered by a physician should be based on a variety of factors including symptoms, medical history and an individual's physical characteristics. Too often, however, decisions are taken out of the hands of physicians and made solely on the basis of cost. We believe there is the potential for conflicts of interest that could influence medical necessity decisions as payers diversify, including through investments and acquisition of technology and medical benefit management companies.

Cardiovascular disease is complex and because there are many different diagnostic tests and treatment approaches, there can be confusion and disagreement, even among clinicians, on the

most appropriate test or course of treatment. One thing clinicians and policymakers should all agree on is that each patient is different, and, therefore, no single imaging modality should ever be considered the first-line test in every patient.

It is necessary that patients get tests and treatments that are appropriate. Medical societies, like ASNC, have partnered with other cardiovascular societies and have invested time and expertise into the development of clinical guidelines, appropriate use criteria and quality measures to guide clinicians toward the appropriate use of diagnostic imaging tests. Yet, these guidelines are often disregarded by payers that use restrictive algorithms that uniformly guide patients to the same diagnostic test regardless of individual characteristics.

Improving Access – Enhancing Rules on Internal Coverage Criteria

ASNC commends CMS' recent regulatory actions related to prior authorization and the criteria MA organizations may use in approving or denying requests for medical care. We appreciate CMS recognizes there is a need to build upon and enhance these regulations, specifically those related to the use of internal coverage criteria.

Using Internal Coverage Criteria to Interpret or Supplement General Provisions

Under existing regulations an MA organization may apply internal coverage criteria when coverage criteria under Traditional Medicare are not fully established in three specific circumstances.[1] CMS explains that one circumstance when it is appropriate to use internal coverage criteria is when additional, unspecified criteria are needed to interpret or supplement "general provisions" to determine medical necessity consistently. CMS also requires that MA organizations must demonstrate the additional criteria the MA organizations apply provide clinical benefits that are "highly likely to outweigh any clinical harms," including from delayed or decreased access to items or services.

ASNC commends CMS for acknowledging existing regulatory text needs to be refined to more clearly state the Agency's intent about interpreting existing policies and to achieve the goal of protecting patients without decreasing access to medically necessary care.

ASNC supports CMS' proposal to replace the term "general provisions" with "the plain language of applicable Medicare coverage and benefit criteria" so it is explicitly evident that internal coverage cannot be used to add new, unrelated coverage criteria for an item or service that already has existing, but not fully established, coverage policies.

CMS states it has found it is difficult to measure the probability the criteria cited and applied by the MA organizations will (or may) have a net positive effect over the potential risks of not

[1] Coverage criteria are not fully established if any of the following occur: (A) Additional, unspecified criteria are needed to interpret or supplement the plain language of applicable Medicare coverage and benefit criteria in order to determine medical necessity consistently; (B) NCDs or applicable LCDs include flexibility that explicitly allows for discretionary coverage in circumstances beyond the specific indications that are listed in an NCD or LCD: (C) There is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria. Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

applying the criteria. Therefore, CMS is proposing to remove the existing requirement that an MA organization must demonstrate the additional criteria provide clinical benefits that are "highly likely to outweigh any clinical harms," including from delayed or decreased access to items or services," and replace it with the requirement that an MA organization must "demonstrate through evidence that the additional criteria explicitly support patient safety."

We appreciate CMS' observations that MA organizations state their internal coverage criteria provide clinical benefits that are highly likely to outweigh any clinical harms, but that information provided by MA organizations that proves this to be true is lacking. Whether CMS changes the language so the MA organization must demonstrate that internal criteria explicitly support patient safety or if the agency retains current language, **the Agency should create clarity around the requirements and methods for MA plans to show the internal criteria explicitly support patient safety or that their use are highly likely to outweigh any clinical harms.**

The term "patient safety" without further context is likely to be met with varied interpretations by MA organizations. The term "patient safety" has been defined as avoiding harm to patients from care that is intended to help them."[2] We recommend CMS expand upon this definition by making clear that "patient safety" includes avoidance of harm from medical care that could have been prevented or lessened with earlier, appropriate care or management. Further, **ASNC recommends CMS' proposed requirement that internal criteria must explicitly support patient safety should be combined with an explicit requirement the internal criteria *also* provide clinical benefit.**

Definition of Internal Coverage Criteria

ASNC supports the proposed additional rules to define and clarify what CMS considers "internal coverage criteria." Specifically, ASNC supports CMS' proposal to define internal coverage criteria as "any policies, measures, tools, or guidelines, whether developed by an MA organization or a third party, that are not expressly stated in applicable statutes, regulations, NCDs, LCDs, or CMS manuals and are adopted or relied upon by an MA organization for purposes of making a medical necessity determination." CMS clarifies in the rule this includes any coverage criteria that restrict access to, or payment for, medically necessary Part A or Part B items or services based on the duration or frequency, setting or level of care, or clinical effectiveness of the care.

CMS states in the rule that in every instance where the plain language of a Medicare coverage rule is interpreted or supplemented it is considered internal coverage criteria, and each instance must be based on current evidence in widely-used treatment guidelines or clinical literature and must be publicly accessible. In previous rule making, CMS finalized that "widely used treatment guidelines" are those "developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions or to determine

[2] Agency for Healthcare Research and Quality. https://psnet.ahrq.gov/patient-safety-101

appropriate level of care."[3] **We recommend CMS modify its description of "widely-used treatment guidelines" to make clear it is referring to medical specialty societies and not entities simply "representing" clinical medical specialists. We believe this added level of clarity and protection for Medicare beneficiaries is needed at a time when health insurers are acquiring physician practices and other provider entities and could therefore claim be an organization representing clinical medical specialties.**

Prohibitions

CMS proposes and ASNC supports two requirements that prohibit the use of all internal coverage criteria.

- internal coverage criterion is prohibited when it does not have any clinical benefit, and therefore, exists to reduce utilization of the item or service; and

- internal coverage criterion is prohibited when the criterion is used to automatically deny coverage of basic benefits without the MA organization making an individual medical necessity determination.

Under current regulations, in instances when a national or local coverage determination is lacking in specificity or clarity, CMS considers internal coverage criteria to be permissible to interpret or supplement general provisions. Oftentimes, multiple imaging modalities may meet Medicare's clinical coverage criteria. In such situations, a health plan or a contracted third party may use internal use internal criteria to automatically deny a test recommended by a patient's physician and instead approve a less expensive diagnostic test. It is critical that in all instances, an MA organization or a contracted third-party reviewer consider a patient's characteristics when making a individual medical necessity determination, as well as medical specialty guidelines or specialty-specific appropriate use criteria.

It has become the practice of some insurance companies to *automatically* deny coverage of positron emission tomography (PET), and other function stress tests, to evaluate stable chest pain and to automatically substitute it with computed tomography angiography (CCTA),[4] even though published, multi-society appropriate use criteria guidelines support PET as appropriate for a range of clinical scenarios.[5,6,7] For example, a physician may recommend PET rather than CCTA to avoid poor image quality and equivocal results in patients with high body-mass index. **ASNC strongly supports the proposed explicit prohibition of MA organizations using internal coverage criteria to systematically deny coverage of basic benefits.**

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[3] Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly
[4] UnitedHealthcare Network Bulletin, May 2020. https://centercare.com/_uploads/UHC-may-2020-network-bulletin.pdf
[5] Schindler T, Bateman T, Berman D, Chareonthaitawee P, Appropriate Use Criteria for PET Myocardial Perfusion Imaging. Mar. 31, 2020. DOI: 10.2967/jnumed.120.246280;
[6] Gulati et. al, AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines, Circulation Volume 144, Number 22; https://doi.org/10.1161/CIR.0000000000001029
[7] Virani S, Newby K, et al. 2023 AHA/ACC/ACCP/ASPC/NLA/PCNA Guideline for the Management of Patients With Chronic Coronary Disease; A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines. CIRCULATION, Volume 148 • Number 9 • 29 August 2023.

Further, these proposed prohibitions are especially necessary given the increasing use by insurance companies and medical benefit management companies of artificial intelligence and other predictive technologies and reports that insurance companies are abusing the use of this technology to deny requests for medical authorization without human review.

In the proposed rule, CMS states it will continue to conduct routine monitoring and auditing of MA organizations, and through these processes, may discover that internal coverage criteria are being used that do not comply with rules or the anti-discrimination rules. In these circumstances, CMS will utilize its current compliance and enforcement processes to determine if any action should be taken for the non-compliance and to remediate the issue. ASNC suggests that health care providers may be best positioned to quickly identify cases in which application of internal criteria by MA organizations do not meet CMS requirements, and we believe the newly proposed transparency requirements will aid greatly in the identification of such cases. **Similar to the mechanism that CMS has created that allows individuals to file a compliance complaint regarding the *No Surprises Act,* we ask CMS to create and share widely a clear process for health care providers or other individuals to file a complaint with CMS when MA organizations are not following internal coverage criteria requirements.**

Public Availability

ASNC supports adding more structure and detail to the public accessibility requirements to ensure MA organizations are making information regarding internal coverage criteria available in a manner that is routinized and easy to follow.

CMS should finalize the following proposals:

- Require MA organizations examine and identify each internal coverage criterion being used and mark or label it as such within their policy documents for readers to understand that the specific internal criterion noted is being applied and may be specific to the MA plan.

- Update the word “criteria” to “criterion” to make it clear that each single coverage criterion used be listed and identified and require the evidence be connected to the internal coverage criterion with a corresponding footnote.

- Require that by January 1, 2026, MA organizations must publicly display on the MA organization’s website a list of all items and services for which there are benefits available under Part A or Part B where the MA organization uses internal coverage criteria when making medical necessity decisions.

<u>Ensuring Equitable Access – Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures</u>

ASNC is grateful for past Agency regulatory actions to address concerns regarding the barriers to care that result from the use of prior authorization by MA organizations. It is clear, however, that greater regulatory actions and oversight are needed.

Based on an August 2024 KFF examination of MA organizations and their use of prior authorization, the number of prior authorization requests (1.7) per MA enrollee across MA organizations remained the same from 2019 to 2022.[8] However, the number of all prior authorization requests that were denied increased significantly from 2021 to 2022 (5.7% in 2019, 5.6% in 2020, 5.8% in 2021, and 7.4% in 2022).[9] The KFF analysis found that for 2022 of those denials appealed (one in 10), the vast majority of appeals (83.2%) resulted in overturning the initial prior authorization denial.[10] Denials eventually approved on appeal represent care that was likely delayed and significant administrative burden on physicians practices fighting with MA organizations to gain approval of medically necessary care.

ASNC strongly supports proposals contained in this rule that build upon the April 2024 CMS final rule[11] with regard to the disclosure by MA organizations of prior authorization data.

Specifically, ASNC supports the disclosure of prior authorization data on an item and service level. Without granular reporting, the true extent of denials and targeted denials may be masked. Reporting at a more granular level is important because there may be many more denials of more expensive tests.When reporting by item and service, data should be as specific as possible. For example, data on prior authorization for imaging should be by modality and condition specific.

Specifically, ASNC supports the following as proposed:

- The percentage of standard prior authorization requests that were approved, reported by each covered item and service.

- The percentage of standard prior authorization requests that were denied, reported by each covered item and service.

- The percentage of standard prior authorization requests that were approved after appeal, reported by each covered item and service.

- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, reported by each covered item and service.

- The percentage of expedited prior authorization requests that were approved, reported by each covered item and service.

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[8] Fuglesten Biniek J, Sroczynski N, Newman P, Use of Prior Authorization in Medicare Advantage Exceeded 46 Million Requests in 2022, KFF. Aug. 8, 2024. https://www.kff.org/medicare/issue-brief/use-of-prior-authorization-in-medicare-advantage-exceeded-46-million-requests-in-2022/
[9] Ibid.
[10] Ibid.
[11] Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE) (April 23, 2024)

- The percentage of expedited prior authorization requests that were denied, reported by each covered item and service.

- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, reported by each covered item and service.

- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, reported by each covered item and service.

Conclusion

ASNC appreciates the Agency's consideration of its comments. **We urge CMS to finalize its proposal related to internal coverage criteria and prior authorization to safeguard against abuses of MA organizations that lead to delayed and denied care for MA plan enrollees.** Any questions or requests for additional information should be directed to Georgia Lawrence, ASNC's Director Regulatory Affairs, at glawrence@asnc.org.

Sincerely,

Panithaya Chareonthaitawee

Panithaya Chareonthaitawee, MD
President,
American Society of Nuclear Cardiology

ASNC is a greater than 5,700 member professional medical society, which provides a variety of continuing medical education programs related to nuclear cardiology, 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.