February 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Submitted via regulations.gov

Dear Administrator Brooks-LaSure:

The American Society of Nuclear Cardiology (ASNC) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule, *Contract Year 2024 Policy and Technical Changes to Medicare Advantage (MA) Program (Part C) and Medicare Prescription Drug Benefit (Part D), etc.* [CMS-4201-P]. ASNC supports the proposals in this rule to alleviate provider administration burden and improve timely beneficiary access to medically necessary care and offers additional comment on the following sections:

- Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools

- Review of Medical Necessity Decisions

ASNC is a greater than 4,700 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

Utilization Management Requirements

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. Far too often, however, decisions are taken out of the hands of physicians and made solely on the basis of cost. We also 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 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 though 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. As CMS acknowledges in the rule, better guardrails are needed to ensure that utilization management tools are used in ways that ensure timely and appropriate access to medically necessary care for beneficiaries enrolled in MA plans.

We ask CMS to finalize the following provisions to ensure minimum coverage requirements are met and that MA plans do not deny or limit coverage of basic benefits to their enrollees:

- codify existing standards for coverage criteria to ensure that basic benefits coverage for MA enrollees is no more restrictive than traditional Medicare;

- prohibit MA organizations from denying coverage of an item or service based on internal, proprietary, or external clinical criteria not found in traditional Medicare coverage policies;

- when coverage criteria are not fully established in applicable Medicare statute, regulation, National Coverage Determination (NCD) or Local Coverage Determination (LCD), an MA plan may create internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available;

- the development of internal policies must follow similar rules that CMS and MACs follow when creating NCDs or LCDs. The process must also be transparent and based on current evidence in widely used treatment guidelines or clinical literature; and

- prohibit MA plans from using prior authorization to delay or discourage care.

With regard to the definition of "widely used treatment guidelines," we support that they represent those guidelines developed by organizations representing clinical medical specialties for the treatment of specific diseases or conditions.

Review of Medical Necessity Decisions

ASNC supports the need to enhance the overall medical necessity decision-making process and the quality of the review conducted at the organization determination level.

In particular for imaging tests, because multiple imaging modalities may meet Medicare's clinical coverage criteria, it is it important a reviewer consider a patient's characteristics, as well as medical specialty guidelines or specialty-specific appropriate use criteria. For example, a physician may recommend positron emission tomography (PET) rather than single-photon emission computed tomography (SPECT) to avoid poor image quality and equivocal results in patients with high body-mass index. This approach is consistent with current practice standards.

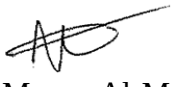
ASNC agrees that during initial medical necessity determinations, the physician or other appropriate health care professional who conducts the review must have expertise in the field of medicine that is appropriate for the item or service being requested — as well as knowledge of including knowledge of Medicare coverage criteria for that particular item or service — before the MA organization or applicable integrated plan issues an adverse determination. **We recommend CMS strengthen this proposed requirement to state decisions must be made by a licensed physician who has expertise in the field of medicine that is appropriate for the item or service, including familiarity with widely used treatment guidelines, and must have knowledge of Medicare coverage criteria for that item or service.**

Conclusion

According to a 2021 survey of physicians conducted by the American Medical Association (AMA), physician practices complete 41 prior authorizations on average per physician, per week. Physicians should be focused on patient care and less on navigating the prior authorization process to get patients their recommended tests, procedures, and treatments. Problems with prior authorization and other utilization management tactics are not isolated to MA plans. We therefore encourage the Agency to use its administrative authorities to similarly address prior authorization, its burden on providers and impact on patient care across payers.

ASNC appreciates the Agency's consideration of its comments and directs questions to Georgia Lawrence, ASNC's Director Regulatory Affairs, at glawrence@asnc.org.

Sincerely,



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