March 20, 2023

Tamara Syrek Jensen
Director
Coverage and Analysis Group Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Syrek Jensen:

As counsel to the Society for Heart Attack Prevention and Eradication (SHAPE), we are writing to object to CMS' denial of SHAPE's January 7, 2019 formal request for a National Coverage Determination (NCD) (hereinafter referred to as NCD Request or the Request) for Coronary Artery Calcium (CAC) scoring when used as a diagnostic test for certain patients at intermediate risk of asymptomatic atherosclerotic cardiovascular disease (ASCVD). In correspondence sent to CMS in April of 2019, SCCT strongly supported the NCD Request.

On February 8, 2022, over three years after the NCD Request was filed and after a number of hearings and correspondence with SHAPE, CMS determined that it did not have the jurisdiction to consider the Request because, at the time the Request was filed, clinical literature as well as two of CMS' "sister agencies" (the Agency for Healthcare Research and Quality, and the United States Preventive Services Task Force [USPSTF]) considered CAC a screening test and that the test is therefore eligible for coverage only if is given a USPSTF grade A or B recommendation (i.e. only as a "preventive health service" under Social Security Act (SSA) §1862(s)(2)(bb).

Based on the analysis set forth below, we strongly disagree with CMS' conclusion that CAC is solely a preventive health service that must be given a USPSTF grade A or B recommendation in order to be eligible for a NCD. Summarizing, SHAPE's NCD request clearly and unequivocally requested coverage for CAC as a diagnostic test under limited clinical circumstances in the context of shared decision making between the patient and physician, and expressly declined to request a NCD for CAC as a screening tool. There is substantial precedent for the same test to be used for both screening and diagnosis, and professional guidelines clearly support the use of CAC for diagnostic purposes. Moreover, CMS failed to follow the procedures mandated by its own guidance document in addressing SHAPE's request. For these reasons and those detailed below, SHAPE requests that CMS consider and approve the NCD Request as expeditiously as practicable. We also request that CMS meet with SHAPE representatives to discuss the process moving forward.

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Relevant Statutory and Regulatory Provisions

Under Part B of the Medicare Act (at SSA § 1861(s)3)), Medicare covers "medical and other health services," which are defined to include:

> diagnostic X-ray tests … diagnostic laboratory tests, and other diagnostic tests;

SSA §1861(s)(**3**) (Emphasis added.). This coverage category is separate and distinct from services covered under various subparagraphs of SSA §1861(s)(**2**)(Emphasis added), which include a number of specific preventive health services:

> (P) prostate cancer screening tests (as defined in subsection (oo));
> (R) colorectal cancer screening tests (as defined in subsection (pp));
> (W) an initial preventive physical examination (as defined in subsection (ww));
> (X) cardiovascular screening blood tests (as defined in subsection (xx)(1));
> (Y) diabetes screening tests (as defined in subsection (yy));
> (AA) [certain] ultrasound screening for abdominal aortic aneurysm (as defined in subsection (bbb)); and
> (BB) additional preventive services (described in subsection (ddd)(1)).

Therefore, Medicare coverage of diagnostic tests is completely separate and apart from Medicare coverage of certain specific screening services, which are specifically enumerated in the Medicare Act.

Likewise, the Medicare regulations implementing the diagnostic test benefit is separate and apart from regulatory provisions related to various screening tests.[1] Unlike screening tests, Medicare regulations specifically require that a diagnostic test be "ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem."[2] The Medicare regulations specifically anticipate that the patient's treating physician is to use the diagnostic test results "in the management of the beneficiary's specific medical problem."

The Medicare Act requires that, to be covered by Medicare, an item or service (including a diagnostic test) must be "reasonable and necessary for the diagnosis or treatment of illness or

[1] Compare 42 CFR §410.32 (diagnostic tests) with 42 CFR§ (cardiovascular disease screening test).
[2] 42 CFR §410.32(a).

injury or to improve the functioning of a malformed body member."[3] While no provision of the Medicare regulations defines the term "reasonable and necessary," Medicare Administrative Contractors (MACs) are directed to determine if an item or service is "reasonable and necessary" under §1862(a) (1) (A) of the Act if the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency in terms of whether the service or item is:
    - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member;
    - Furnished in a setting appropriate to the beneficiary's medical needs and condition;
    - Ordered and furnished by qualified personnel; and
    - One that meets, but does not exceed, the beneficiary's medical need.

See Medicare Program Integrity Manual, Chapter 13, §13.5.4.

The NCD Request addresses each of these "reasonable and necessary" criteria. As set forth in the AHA/ACC Cholesterol Management Guidelines, a CAC is a safe and effective test for guiding the initiation of statin therapy for certain patients in the Intermediate Risk Category and its use for this indication is not experimental or investigational.[4] When furnished in accordance with the AHA/ACC Cholesterol Management Guidelines, CAC testing meets accepted standards of medical practice for the diagnosis of ASCVD. The test may be appropriately performed in a number of settings, including hospitals and non-hospital facilities (such as Independent Diagnostic Testing Facilities and certain radiology and cardiology offices).

Section 1862(l) of the Medicare Act specifically addresses the processes to be used by CMS in making both NCDs and Local Coverage Determinations (LCDs). Section 1862(l)(2) of the Act requires that, where neither a technology assessment nor deliberation of the Medicare Coverage Advisory Committee is required, as in the case with SHAPE's NCD request, a decision on a request for a NCD must be made within six months of the request. The Act (at SSA

[3] SSA §1862(a) (1) (A).
[4] Arnett, DK., Blumenthal, RS, Albert, MA, et al. *2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines.* Circulation. Vol 140. Issue 11. Pages e596-e646. https://www.ahajournals.org/doi/epub/10.1161/CIR.0000000000000678.

§1862(l)(3)) further outlines the process to be used by CMS in making NCD determinations, requiring publication of the request on the CMS website; publication of the draft proposed decision; a 30-day public comment period and a 60-day deadline for publication of the final decision after close of the public comment period. The final decision must include summaries of public comments, publication of the clinical evidence and other data used in making the decision, and, in the case of positive decisions, a methodology for coding and implementation of coverage. Where (as here), the request is not referred for a technology assessment or MAC deliberation, CMS is required to consult with outside experts (SSA Section 1862(l)(4).

On August 13, 2013, CMS published revised procedures for requesting a NCD (NCD Guidance Document), which states that a formal request for a NCD will be considered "final" if it meets the following requirements:[5]

- The request is in writing.
- The request clearly identifies the statutorily-defined benefit category to which the requester believes the item or service applies and contains enough information for us to make a benefit category determination.
- The request is accompanied by sufficient, supporting evidentiary documentation.
- The information provided addresses relevance, usefulness, or the medical benefits of the item or service to the Medicare population.
- The information fully explains the design, purpose, and method of using the item or service for which the request is made.

The Guidance Document specifically states that, if CMS determines that the request is not complete, the agency "[notifies] the requester and explain our rationale, so the requester has the opportunity to provide missing information."[6] Upon acceptance of the formal request, a tracking sheet is published to enable the public to participate in the NCD process.

I. Analysis

A. The Process Used by CMS to Address the NCD Request is Inconsistent with the Medicare Act and the NCD Guidance Document

The process used by CMS to consider the NCD Request is clearly inconsistent with the procedural requirements set forth in the governing statute and in the NCD Guidance Document.

[5] 78 Federal Register No. 152 48164 et seq. (August 7, 2013) at 48166.
[6] *Id* at 48168.

As set forth above, where (as here) no external Technology Assessment or referral to the MCAC is required, a final decision must be made within six months of a request. In this case, CMS failed to make a decision for over three years following submission of the request and—when a decision was finally made—it was made on the basis of AHRQ and USPSTF assessments and clinical literature that was available at the time the Request was filed. CMS further failed to comply with statutory and NCD Guidance Document provisions that impose various time deadlines; that require a NCD request to be subject to public comment; and that require publication of the clinical evidence supporting a NCD determination. Rather, CMS took over three years to decide that it would not even "open" the NCD process.

B. CMS' Determination Erroneously Classifies CAC solely as a Screening Test That Is Eligible for Coverage Only as a Preventive Health Service

SHAPE's formal request for a NCD was submitted on January 7, 2019, over four years ago. The cover letter accompanying the request clearly requests CMS coverage in conjunction with shared provider-patient decision making for certain patients in the Intermediate Risk Category for ASCVD, the underlying cause of heart attacks. This is the same indication for CAC which is now strongly supported by the 2018 Cholesterol Management Guideline, the 2019 Prevention Guidelines, and the 2020 National Lipid Association Guideline. At the same time, the Request clearly acknowledges that "there needs to be more research done on the subject of using CAC for mass screening to improve ASCVD outcomes." Therefore, from the inception, SHAPE's intention to seek coverage of CAC as a diagnostic test and not as a generalized screening tool, was clear.

This distinction was emphasized by the letter of support submitted by the SCCT several months after the Request was filed. Both that support letter and SHAPE's initial application rely principally on a 2018 modification of the American College of Cardiology/American Heart Association Guidelines for the Management of Cholesterol (AHA/ACC Cholesterol Management Guidelines) which recommend CAC measurement in the context of shared decision making when the decision about starting statin therapy is uncertain from the patient or provider perspective. As noted in the SCCT letter of support:

"Importantly, with the new [AHA/ACC Cholesterol Management Guidelines], the role of CAC has shifted from a "screening test" – where it was used to identify higher risk patients among those who would otherwise be classified as low-risk - to a test which is used in the context of shared decision making among individuals who meet criteria for statin consideration, but for whom there is uncertainty regarding risk and/or patient indecision." (Emphasis added.)

CMS scheduled a hearing on the request for April 30, 2019, and, in advance of that hearing, in correspondence dated April 25, 2019, SHAPE again clarified that it was not requesting coverage of CAC as a screening tool, stating:

> "[W]e respectfully request that CMS considers National Coverage Determination (NCD) for CAC testing in primary prevention of CVD only in patients under Intermediate Risk Category. In other words, we do not recommend CAC for mass screening. The Guidelines are clear that CAC testing should be used for clinical indications in which a patient is categorized as Intermediate Risk and a shared decision making between the patient and care-provider is warranted."

Subsequent meetings and presentations with CMS were held on October 31, 2019 and June 30, 2020, during which SHAPE repeatedly and consistently emphasized that its NCD Request encompassed only diagnostic indications, and not screening.

Despite these interactions, in a letter to SHAPE dated February 8, 2022—three years after the initial NCD Request was filed—CMS stated:

> "When CMS commenced the customary in-depth clinical evidence review on CAC testing, the universe of the evidence as well as the positions of our sister agency, the Agency for Healthcare Research and Quality, and the United States Preventive Services Task Force (USPSTF) consistently characterized CAC testing as screening or preventive. Because of this characterization in the evidence and the limits of our authority under the Medicare statute, which does not allow for coverage of screening or preventive services except for under certain circumstances (i.e., expressly mentioned in the statute or given a USPSTF grade A or B recommendation), CMS cannot open a NCD on CAC testing."

CMS' February 8 decision outlined in the agency's letter is unsupportable for a number of reasons.

First, as was clear from the initial request and subsequent interactions, SHAPE's NCD Request was never intended to request Medicare coverage of CAC as a screening tool. The very first sentence of CMS' February 8 letter itself acknowledges as much, by thanking SHAPE for meeting with CMS on January 20, 2022 to discuss the status of SHAPE's NCD Request for CAC testing "as a diagnostic tool."

Second, neither AHRQ nor the USPSTF assessments, both of which are cited by CMS as support for its characterization of CAC as a screening test, support CMS' conclusion. The AHRQ

assessment, entitled "Noninvasive Testing for Coronary Artery Disease"[7] is dated March 2016, nearly three years before SHAPE's NCD Request and includes the following disclaimer:

> "Archived: This report is greater than 3 years old. Findings may be used for research purposes, but should not be considered current."

In fact, the AHRQ study did attempt to assess CAC as a diagnostic test for those with intermediate risk of ASCVD. Of the nine studies identified in populations with an intermediate pretest risk of CAD, two noncomparative studies reported on the predictive accuracy of coronary artery calcium scoring (CACS) in the diagnosis of CAD. In terms of test-positive patients, the frequency of any cardiac event was substantially higher in both studies (5 and 8 per 100 people) compared with those who tested negative (0 and 1 per 100 people). The registry study also reported a higher risk of both mortality (1.8% vs. 0.4%) and MI (1.1% vs. 0.2%) in those who tested positive. Therefore, the AHRQ report does not support CMS' conclusion that CAC can be assessed only as a screening tool.

The USPSTF assessment related to CAC, entitled "Cardiovascular Disease: Risk Assessment With Nontraditional Risk Factors,"[8] did not purport to evaluate the utility of CAC as a diagnostic tool for those with intermediate risk of ASCVD. Rather, the USPSTF assessment analyzed the clinical evidence supporting the addition of CAC to the existing screening tools in the general public, regardless of risk stratification. Moreover, the USPSTF assessment was released prior to the AHA/ACC Management Guidelines and did not take into account a number of important clinical studies cited in these Guidelines or consider the utility of CAC in the context of a shared patient decision-making model.

Third, CMS' determination appears to assume that a test can be characterized as either a screening test or diagnostic test based solely on the nature of the technology. In fact, the same technology can be utilized for either screening or diagnostic purposes, and it is the purpose of the test and the way the test results are used in the detection and management of a patient condition that should be considered in distinguishing between a screening test and a diagnostic test. While screening is utilized in an asymptomatic and undifferentiated patient population in order to detect the potential need for additional diagnostic testing, a diagnostic test is typically used to further guide treatment decisions in a patient who is either symptomatic or, if asymptomatic, is at increased risk for an illness or other condition.

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[7] https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/coronary-artery-disease-testing_research.pdf.
[8] Risk Assessment for Cardiovascular Disease With Nontraditional Risk Factors US Preventive Services Task Force Recommendation Statement. JAMA. 2018;320(3):272-280. doi:10.1001/jama.2018.8359. https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/cardiovascular-disease-screening-using-nontraditional-risk-assessment.

For example, Medicare covers mammography both as a screening test and as a diagnostic test:[9] Under the applicable NCD, a diagnostic mammogram may be eligible for coverage if:

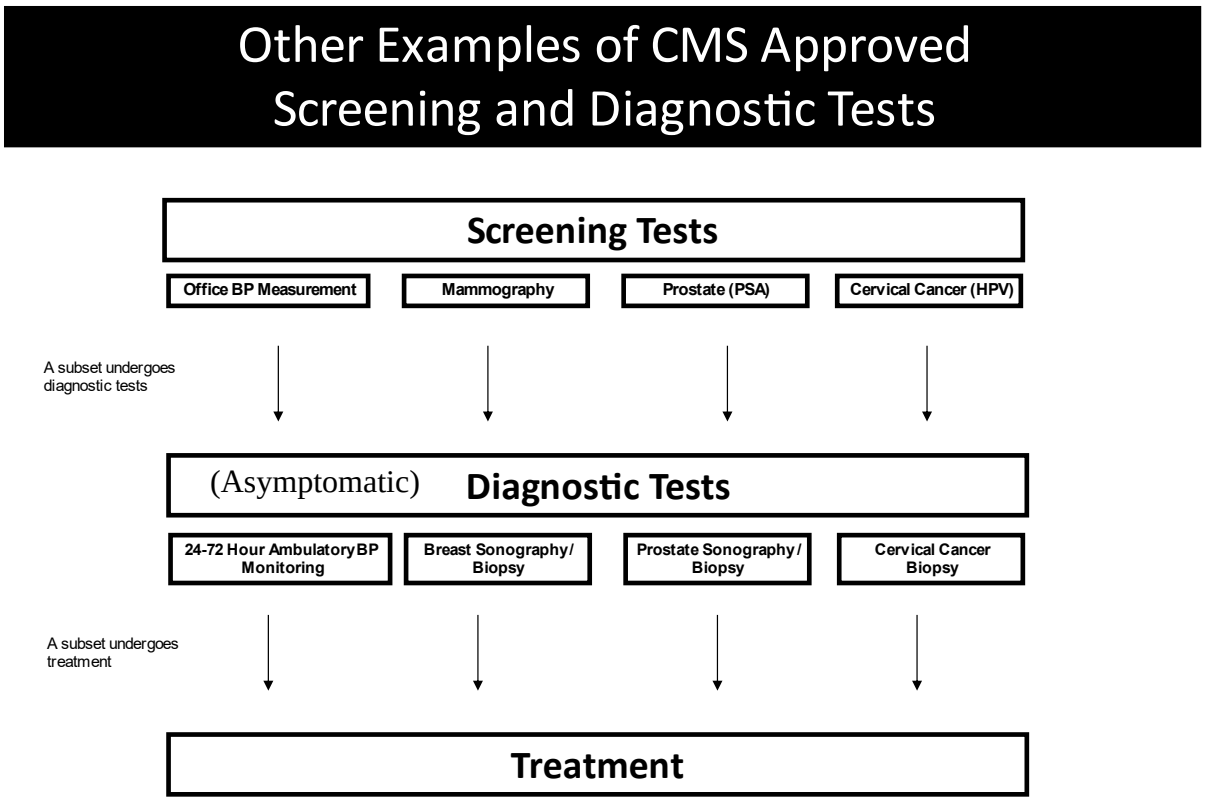
- A patient is asymptomatic but, on the basis of the patient's history and other factors the physician considers significant, the physician's judgment is that a mammogram is appropriate. (Medicare Benefit Policy Manual Section 220.4)

Likewise, CAC may be utilized either as a screening or as a diagnostic tool depending on a particular patient's risk factors as further delineated in the AHA/ACC Cholesterol Management Guidelines. As per current guidelines, when patients already meet Guideline indications for cholesterol lowering therapy, the use of CAC testing is not to screen them, but rather for shared decision making in selected cases where there is uncertainty regarding their risk / benefit of treatment.

Fourth, the primary purpose of CAC when utilized as a screening tool is different from its purpose when used as a diagnostic tool for the intermediate risk population. Screening is generally performed in order to identify those for whom further testing (and potential therapeutic intervention) may be appropriate. On the other hand, the primary purpose of CAC when used as a diagnostic tool is to support a decision to defer treatment (statins) for patients in the Intermediate Risk Category with a zero CAC score for whom statins otherwise would be prescribed. There is a large group of people in the Intermediate Risk Category whose calcium score is zero despite having risk factors. The 2018 AHA/ACC Cholesterol Management Guidelines suggest deferral of statin therapy in these patients. This accounts for about 50% of the population that are currently (and blindly, only based of risk factors) recommended to take statin drugs. Many of Medicare population fall in this group and SHAPE's proposal (similar to the above AHA/ACC Guidelines) is to not recommend statin therapy in this group.

Fifth, CAC must not be characterized as a screening test solely because the intermediate risk patient population for whom the test should be performed are asymptomatic. The majority of these patients are hyperlipidemic patients who are classified under International Classification of Diseases (ICD 10) **E78. 5.**While screening is generally performed on an asymptomatic patient population, many diagnostic tests are performed for patients who are asymptomatic. Consider the schematic below:

[9] SSA §1834(c) (screening mammography); SSA §1861(s)(3)(diagnostic mammography).



In light of these precedents, CAC cannot be characterized as screening rather than diagnostic solely on the grounds that the patients involved are asymptomatic.

Finally, SHAPE's request (and the AHA/ACC Cholesterol Management Guidelines) recommend the performance of CAC for Intermediate Risk Classification patients only if risk assessment is uncertain and only in the context of joint patient/provider shared decision making. A screening tool generally is performed as a public health initiative outside the context of an individual patient-physician encounter involving individualized decision making.

For each of these reasons, we do not believe that CMS' determination that the agency lacks the authority to consider the NCD Request is supportable. Since the NCD Request requests a NCD addressing coverage of CAC for a particular patient population in the context of individualized decision making regarding whether statins can be safely deferred, CMS has the authority to consider the Request as an NCD Request for a diagnostic test. Since coverage of CAC as a preventive health service is not at issue, a USPSTF grade A or B is not statutorily required.

C. CMS' dismissal of SHAPE's NCD Request Exacerbates Health Disparities and is Inconsistent with the Biden Administration's Health Disparities Initiatives

On January 20, 2021, The President of the United States issued the Executive Order On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, which states in relevant part:

> "It is therefore the policy of my Administration that the Federal Government should pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality."

Cardiovascular mortality is not only on the rise in the US but is predicted to increase markedly, particularly in our minority population, in the next few decades.[10] Because CAC currently is not covered by the Medicare Program, the test is currently accessible only to those who can pay for it out of pocket, exacerbating current racial and socioeconomic disparities in access to effective treatment for coronary artery disease. One recent study[11] focusing on access to CAC in the Chicago area found:

> "Health care disparities based on socioeconomics and/or race have resulted in cardiovascular disease and events that are greater in the [African American] population. Although there are multiple manifestations of structural racism that seem to contribute to these disparities, it has been noted for many years that cardiovascular disease testing and treatment have been underutilized, along with less prevention and management of disease."

In addition, low socioeconomic position (SEP) is associated with increased prevalence of cardiovascular disease, and there is a positive association between SEP and coronary artery calcium score (CAC) in a population presenting with symptoms suggestive of obstructive coronary artery disease. This strongly suggests that the use of CAC would be particularly useful in the management of patients with a low SEP.[12]

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[10] Mohebi R., Chen, C . , Ibraham NE, et al. *Cardiovascular Disease Projections in the United States Based on the 2020 Census Estimates.* J. Am. Coll Cardiol.. 2022 Aug, 80 (6) 565–578 (https://www.jacc.org/doi/abs/10.1016/j.jacc.2022.05.033.

[11] Mashaal Ikram a, Kim A. Williams S. *Socioeconomics of coronary artery calcium: Is it scored or ignored?* Journal of Cardiovascular Computed Tomography 16 (2022) 182–185.

[12] Nissen L, Winding TN, Schmidt SE, Hasan Shafi B, Bossano Prescott EI, Nyegaard M, Winther S, Bøttcher M. Association between socioeconomic position and coronary artery calcium score in patients with symptoms suggestive of obstructive coronary artery disease. J Cardiovasc Comput Tomogr. 2023 Feb 14:S1934-

II. Conclusion

For all of the reasons set forth above, we urge CMS to reverse its February 8, 2022 determination that it lacks the jurisdiction to open a NCD on CAC when used as a diagnostic test as set forth in the NCD Request, and that it consider and approve the NCD Request as expeditiously as practicable. We also request that CMS meet with SHAPE representatives to discuss the process moving forward.

We appreciate your consideration of this matter and look forward to hearing from you.

Sincerely,

Diane Millman

5925(23)00050-3. doi: 10.1016/j.jcct.2023.02.001. Epub ahead of print. PMID: 36797085.https://pubmed.ncbi.nlm.nih.gov/36797085/.