



# SHAPE

**Mission: Eradicating Heart Attacks**

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**Mission:**

*To eradicate heart attacks by  
championing new strategies  
for prevention while  
advancing the scientific quest  
for a cure.*

Meena Seshamani, M.D., Ph.D  
Deputy Administrator and Director  
Center for Medicare

August 4, 2022

RE: National Coverage Determination request for coronary artery calcium testing as a diagnostic tool

Dear Dr. Seshamani:

On behalf of the Society for the Prevention and Eradication of Heart Attacks, please accept our congratulations on your appointment as the Deputy Administrator of CMS and Director of the Center for Medicare. You are leading the largest healthcare coverage program in the nation whose policies can affect millions of people.

The purpose of this letter is to bring to your attention what we believe to be an error by Medicare's Coverage and Analysis Group in considering our formal proposal for a National Coverage Determination (NCD) of coronary artery scoring (CAC) as a diagnostic tool.

After a decade of data review and thorough evaluation, in November 2019, the American Heart Association and American College of Cardiology jointly updated the CVD prevention guidelines and recommended the use of CAC testing in shared decision making between the clinician and patient. Subsequently, on January 7, 2019, we took the initiative to submit a formal proposal for National Coverage Determination of CAC. After three years, and several hearings, CMS formally responded with the attached letter. The letter contradicts itself, as it acknowledges that our formal NCD proposal was as a "diagnostic" tool, which we proposed for a subset of patients who fall in the ASCVD Intermediate Risk Category. However, the denial of the coverage was based on the use of CAC as a "screening" tool. After three years, it is disappointing to see CMS judge our request for coverage of CAC as a diagnostic tool using standards set for screening procedures.

We have reached out to the Coverage and Analysis Group for a more thorough explanation for its action but have not received a response.

Unfortunately, this matter has become a source of health disparity. With the rise in public awareness of the value of CAC testing, many physicians are recommending it to their patients. However, only those who can afford to pay for the test can get it. Knowing that CVD is the leading cause of death in the US and disproportionately affects low-income populations, it is imperative that CMS rectify its mistake and open NCD for diagnostic CAC testing. In this connection, we note that CAC diagnostic testing costs a fraction of diagnostic cardiac stress testing which is known to be overused. By opening an NCD for diagnostic CAC, CMS can also evaluate the potential for reducing unnecessary stress testing in the low-risk CAC negative patients.

We look forward to hearing from you.

Sincerely yours,

  
Valentin Fuster, M.D., Ph.D.  
Physician-in-Chief, Mount Sinai Hospital  
Editor-in-Chief, Journal of the American College of Cardiology  
Past President, American Heart Association  
Past President, World Heart Federation



February 8, 2022

Morteza Naghavi, MD  
President  
Society for Heart Attack Prevention and Eradication (SHAPE)

Valentin Fuster, MD, Ph.D.  
Distinguished Advisor  
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*Via email: [morteza.naghavi@shapesociety.org](mailto:morteza.naghavi@shapesociety.org), [valentin.fuster@mountsinai.org](mailto:valentin.fuster@mountsinai.org)*

Dear Dr. Naghavi and Dr. Fuster,

Thank you for meeting with CMS on January 20, 2022 to discuss the status of your National Coverage Determination (NCD) request for coronary artery calcium (CAC) testing as a diagnostic tool. We appreciate your sincere interest in improving the lives of Medicare beneficiaries through stroke prevention. As discussed during the call, CMS will not be able to open an NCD on CAC testing for statutory reasons at this time.

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 an NCD on CAC testing.

Nevertheless, we are under the impression that there are certain uses of CAC testing that are coverable for beneficiaries at the local Medicare Administrative Contactor level.

Thank you for your patience as CMS followed the customary evidence review process on this topic and understanding when we presented the findings of our evidence review and our statutory limitations. In the event the evidence on this test changes in the future, you are welcome to submit a new NCD request following the process available here:

<https://www.cms.gov/Medicare/Coverage/DeterminationProcess/howtorequestanNCD>. If you have any questions, please reach out to Linda Gousis at [Linda.Gousis@cms.hhs.gov](mailto:Linda.Gousis@cms.hhs.gov).

Sincerely,

Tamara Syrek Jensen, JD  
Director  
Coverage and Analysis Group