



Valentin Fuster, M.D., Ph.D.
Chief Medical Advisor

Morteza Naghavi, M.D.
CEO

JoAnne Zawitoski, J.D.
Chairwoman

Scientific Advisory Board:

Arthur Agatston, M.D.
Daniel Berman, M.D.
Ron Blankstein, M.D.
Michael Blaha, M.D.
Matthew Budoff, M.D.
Jay Cohn, M.D.
Raimund Erbel, M.D.
Erling Falk, MD, Ph.D.
Zahi Fayad, Ph.D.
Sergio Fazio, M.D.
Philip Greenland, M.D.
Craig Hartley, Ph.D.
Harvey Hecht, M.D.
Howard Hodis, M.D.
Ioannis Kakadiaris, Ph.D.
Sanjay Kaul, M.D., M.P.H.
Asher Kimchi, M.D.
Robert Kloner, M.D., Ph.D.
Wolfgang Koenig, M.D., Ph.D.
Iftikhar J. Kullo, M.D., Ph.D.
Daniel Lane, M.D., Ph.D.
David Maron, M.D.
Roxanna Mehran, M.D.
Ralph Metcalfe, Ph.D.
Tasneem Naqvi, M.D.
Koen Neiman, M.D.
Jagat Narula, M.D.
Khurram Nasir, M.D., M.P.H.
Paolo Raggi, M.D.
George P. Rodgers, M.D.
James HF Rudd, Ph.D.,
John Rumberger, M.D., Ph.D.
Leslee Shaw, Ph.D.
Henrik Sillisen, M.D., Ph.D.
David Spence, M.D.
Robert Superko, M.D.
Pierre-Jean Touboul, M.D.
Nathan Wong, Ph.D.

Secretary:
Brenda Garret Super, CVRN

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

Joseph Chin, M.D.
Deputy Director
Coverage and Analysis Group
Center for Medicare and Medicaid Services

November 1, 2023

Dear Dr. Chin,

On behalf of our group, I'm writing to request a follow-up Zoom meeting based on the following:

1) In your latest response regarding our request for national coverage of coronary artery calcium (CAC) scan, you stated:

“We recognize that SHAPE’s request was regarding diagnostic use, and with that use in mind, CMS medical officers identified that there was not yet a substantial, persuasive body of clinical evidence on the narrow use of CAC as a diagnostic test to reclassify risk for Intermediate Risk Category patients that also showed subsequent improved health outcomes for these select patients.”

To our knowledge, CMS has not applied such a requirement to any other diagnostic tests including other imaging modalities such as echocardiography, SPECT, PET or cardiac MRI. We respectfully request your justification.

2) Since our last Zoom meeting, there has been breakthrough development in the applications of AI to CAC scans. The new development has resulted in a significant improvement in the diagnostic value of CAC scans for patients at risk of atrial fibrillation, stroke and heart failure. This value is in addition to the value of CAC scans for coronary heart disease based on coronary artery calcium score. Recently FDA has granted “Medical Device Breakthrough Designation” to the AI-powered CAC. We would like to discuss the new development with your team and if necessary, to apply for NCD under “Coverage with Evidence Development”.

I look forward to your response.

Sincerely yours,

DocuSigned by:
Dr. Valentin Fuster
7155A2150E1745F...

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