Society for Heart Attack Prevention and Eradication
SHAPE
Mission: Eradicating Heart Attacks

Sent via Email and Certified Mail



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

**April 25, 2019**

**David Dolan**
**Centers for Medicare & Medicaid Services**
**Center for Clinical Standards and Quality**
**Coverage and Analysis Group**
**(410) 786-3365**
**david.dolan@cms.hhs.gov**

**Subject: Proposed Agenda for CMS Hearing of SHAPE's Formal Request for a National Coverage Determination for Coronary Artery Calcium (CAC) Testing**

Dear Mr. Dolan,

On behalf of myself and my colleagues, I would like to thank CMS for considering our proposal and scheduling a formal hearing on April 30th, 2019 3:00 pm – 4:00 pm ET.

For the agenda of the meeting, we would like to discuss the following:

1) The 2018 Cholesterol Guidelines supported by the following 12 medical organizations:

## AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol

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2) The 2019 Prevention Guidelines issued by American College of Cardiology and American Heart Association:

## 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease

2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease

WRITING COMMITTEE MEMBERS, Donna K. Arnett, PhD, MSPH, FAHA, Co-Chair, Roger S. Blumenthal, MD, FACC, FAHA, Co-Chair, Michelle A. Albert, MD, MPH, FAHA, Erin D. Michos, MD, MHS, FACC, FAHA, Andrew B. Buroker, Esq, Michael D. Miedema, MD, MPH, Zachary D. Goldberger, MD, MS, FACC, FAHA, Daniel Muñoz, MD, MPA, FACC, Ellen J. Hahn, PhD, RN, Sidney C. Smith, Jr., MD, MACC, FAHA, Cheryl D. Himmelfarb, PhD, RN, ANP, FAHA, Salim S. Virani, MD, PhD, FACC, FAHA, Amit Khera, MD, MSc, FACC, FAHA, Kim A. Williams, Sr., MD, MACC, FAHA, Donald Lloyd-Jones, MD, SCM, FACC, FAHA, Joseph Yeboah, MD, MS, FACC, FAHA, J. William McEvoy, MBBCh, MEd, MHS, Boback Ziaeian, MD, PhD, FACC, FAHA, ACC/AHA TASK FORCE MEMBERS, Patrick T. O'Gara, MD, MACC, FAHA, Chair, Joshua A. Beckman, MD, MS, FAHA, Chair-Elect, Glenn N. Levine, MD, FACC, FAHA, Immediate Past Chair, Sana M. Al-Khatib, MD, MHS, FACC, FAHA, Mark A. Hlatky, MD, FACC, FAHA, Kim K. Birtcher, PharmD, MS, AACC, John Ikonomidis, MD, PhD, FAHA, Joaquin E. Cigarroa, MD, FACC, José A. Joglar, MD, FACC, FAHA, Anita Deswal, MD, MPH, FACC, FAHA, Laura Mauri, MD, MSc, FAHA, Lee A. Fleisher, MD, FACC, FAHA, Mariann R. Piano, RN, PhD, FAHA, Federico Gentile, MD, FACC, Barbara Riegel, PhD, RN, FAHA, Zachary D. Goldberger, MD, MS, FACC, FAHA, Duminda N. Wijeysundera, MD, PhD

3) The above guidelines were based on many longitudinal follow-up studies mostly funded by the NIH that showed CAC testing can significantly improve CVD risk assessment. It does so by downgrading or upgrading risk

   3.1) On the one hand, CAC identifies individuals whose risk factors (e.g. high cholesterol) are not alarmingly high and they are currently categorized as Intermediate Risk, yet their coronary arteries have a great amount of calcification. Many in this group go on to have an adverse CVD event. CAC appropriately reclassifies them from Intermediate to High Risk.

   3.2) On the other hand, there is a large group of people in the Intermediate Risk category whose calcium score is zero despite having risk factors. The new guidelines suggest deferral of statin therapy in these patients. This accounts for about 50% of the population that are currently recommended to take statin drugs based on their risk factors. Many of the Medicare population fall in this group, and our proposal (similar to the above guidelines) is to defer statin therapy in this group. This overtreatment has been demonstrated again and again in multiple studies as cited by the guidelines and SHAPE Task Force Report (citations attached). Adoption of a personalized approach based on CAC test can lead to reducing cost and potential side effects of these drugs, particularly in the elderly population. It is important to highlight that the net benefit of statin drug therapy is less persuasive as the age goes up. Therefore, a personalized approach to recommend therapy only to those with evidence of subclinical atherosclerotic cardiovascular disease (ASCVD) makes sense.

4) Based on the indisputable evidence cited by the guidelines, all 12 leading national organizations (ACC/AHA/AACVPR/AAPA/ABC/ACPM/ADA/AGS/ APhA/ASPC/NLA/PCNA) have agreed to elevate CAC testing to a level II-a recommendation in Intermediate Risk patients. The II-a class applies to standard of care diagnostic and therapeutic actions that practitioners are urged to follow for best practices

and to minimize legal consequences of malpractice lawsuits. Lack of reimbursement for such a critical test can lead to troubling situations both for patients and healthcare providers.

5) In conclusion, we respectfully request that CMS consider National Coverage Determination (NCD) for CAC testing in primary prevention of CVD only in patients in the 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 shared decision-making between the patient and healthcare provider is warranted.

I look forward to meeting you at the hearing on April 30th, 3:00 PM EST.

Please find enclosed supporting documents along with the list of participants in person and via phone.

Sincerely yours,

On behalf of the SHAPE Task Force and Advisory Board,

Morteza Naghavi, M.D.