POLICY GUIDANCE
FEBRUARY 2019

American Heart Association.

Expanding Coverage of Cardiac Computed Tomography for Calcium Scoring

Background

Cardiac computed tomography, commonly known as a cardiac CT scan, is utilized to take images of a patient's beating heart to visualize their cardiac anatomy, coronary circulation and great vessels. Cardiac CT scans are commonly used by clinicians to evaluate the state of a patient's heart muscle, coronary arteries, pulmonary veins, pericardium, and thoracic and abdominal aorta.[1]

While the clinical indications for ordering a cardiac CT vary and there are many diagnostic imaging modalities to consider in practice, one potential application of the technology involves non-invasive, cross-sectional scanning of the vessels that supply blood to the heart muscle to measure the presence and amount of calcium-containing plaque. Known as a coronary artery calcium (CAC) test, the scan produces a patient-specific "score" that is designed to estimate, on a scale of 0 to over 400, the risk or extent of coronary artery disease based on the number, size and density of calcified plaque deposits in the coronary arteries. The higher the score, the greater the risk for having a heart attack, experiencing a stroke or dying from one of these adverse events in the next 10 years.

Statement of the Problem

While numerous studies have indicated that CAC tests, with an approximate cost of between $100 and $400[2], are a reliable measure of certain patients' relative risks for adverse cardiac (e.g., heart attacks) and neurological (e.g., strokes) events, most public and private payors heavily restrict coverage of the procedure and require a majority of patients, despite the procedure's proven benefits and relatively low risk profile, to pay for it on an elective, out-of-pocket basis.

Impetus for Action

In November 2018, the joint American College of Cardiology (ACC)/American Heart Association (AHA) Task Force on Clinical Practice Guidelines issued new cholesterol-related recommendations supporting the use of cardiac CT scans to produce CAC scores for certain at-risk patients.[3] The newly-released guidelines lead clinicians through a process, using a calculated formula and taking into account known risk factors, to place a patient in one of four classifications of risk: low, borderline, intermediate or high. For patients classified as an "intermediate risk" for having or developing atherosclerotic cardiovascular disease (ASCVD), the guidelines suggest that patients and clinicians consider CAC scoring as a tool for providing a greater degree of certainty as to whether statin use is medically necessary and clinically appropriate to prevent or decrease the risk of an adverse event. For individuals classified as a "borderline risk" for having or developing ASCVD, CAC scoring may also be useful to more accurately predict an individual's risk if: uncertainty exists related to the most appropriate clinical and/or lifestyle interventions to help reduce a

[1] https://my.clevelandclinic.org/health/diagnostics/16834-cardiac-computed-tomography
[2] https://www.heart.org/en/news/2018/11/13/coronary-calcium-test-could-help-clarify-heart-disease-risk-and-control-cholesterol
[3] https://www.ahajournals.org/circ/doi/10.1161/CIR.0b013e3181fcae66

patient's risk; and/or the calculated risk of the patient having or developing ASCVD is still unknown or open to different interpretations, despite having been produced utilizing a formal risk estimation mechanism consistent with existing ACC/AHA methodologies.

Policy Position

Given the existing body of evidence on the procedure's cost- and clinical-effectiveness in certain situations, the AHA support efforts to expand coverage of and appropriate payment for CAC tests across the payor continuum, especially for patients who might benefit from knowing their score and having it considered in care decisions made by their physician or team of healthcare providers, including:

- Men and women of all ages with high cholesterol who are reluctant to begin statin therapy and who want to understand their risks and potential benefits of medication therapy more precisely;
- Men and women of all ages with high cholesterol who are concerned about re-starting statin therapy after stopping treatment because of side effects;
- Men ages 55 to 80 or women ages 60 to 80 with high cholesterol, but few or no other risk factors for having or developing ASCVD, who question whether they would benefit from statin therapy; and
- Men and women ages 40 to 55 with a calculated 10-year risk estimate for ASCVD between 5 percent and 7.5 percent, as calculated using the ASCVD Risk Calculator, and added risk factors (e.g., smoking, hypertension, diabetes, being overweight, lack of physical activity) that increase their chances of having or developing coronary artery disease.

The ACC/AHA do not generally recommended CAC testing of asymptomatic patients who are classified as "low risk" or "high risk" as the score is unlikely to provide any new or additive information that would be useful in defining a patient's risk or directing a personalized treatment plan.

Stakeholders

Public and private payors often have significant authority to decide which tests to cover under the terms of their respective health benefit plans. Of paramount importance in weighing any coverage-related decisions are the cost-and clinical-effectiveness of a specific test. As it pertains to coverage of cardiac CTs for calcium scoring, most payors have previously concluded that the body of evidence on the procedure's cost- and clinical-effectiveness failed to demonstrate a proven benefit to patients should it be covered and paid for. With the recent publication of the ACC/AHA guidelines, however, space may exist within the policy arena to advocate for the inclusion of CAC tests under beneficiaries' benefit plans and the appropriate payment of providers and facilities performing these tests. In approaching payors, absent a mandate on the federal level that applies to all coverage arrangements, the following stakeholders must be targeted in a market-specific fashion:

Stakeholder	Impact / Scope	Oversight Control	Policy Mechanism(s)
Federal legislative and regulatory bodies (e.g., U.S. Congress, U.S. Department of Health &	• Medicare • Medicaid • Private Insurance	• Plans regulated in part or in full by federal laws and/or regulations (e.g., Public Health	• Legislative mandates • Regulatory fixes

Human Services, Department of Labor)		Service Act (PHSA), Employee Retirement Income Security Act (ERISA), Internal Revenue Code (IRC), Social Security Act (SSA))	• Technical changes via sub-regulatory means
State legislative and regulatory bodies	• Medicaid • Private insurance	• Plans regulated in part or in full by state laws and/or regulations	• Legislative mandates • Regulatory fixes • Technical changes via sub-regulatory means • Requests to the federal government via waivers to • Selection of benchmark plans with existing cardiac CT coverage standards
Employers sponsoring and/or offering insurance to employees	• Employer-sponsored plans, including self-funded or fully-insured options that allow for customization	• Individual employers' plans	• Working directly with several large employers to pilot the inclusion of CAC testing into their plans

AHA Policy Approaches for Consideration

Mechanism	*Impacted Market(s)*	*Explanation / Notes*
Formal submission of a National Coverage Determination (NCD) request to the Centers for Medicare & Medicaid Services (CMS)	Medicare	On the federal level, the Centers for Medicare and Medicaid Services (CMS) periodically issues or reviews Medicare coverage decisions through federal directives known as NCDs. Reviews of petitioners' requests undergo an extensive review, with opportunities for public participation, involving a close examination of any supporting evidentiary documentation provided as a component of the request and information provided that addresses the relevance, usefulness, and/or benefits of the item or service to the Medicare population. The Society for Heart Attack Prevention & Eradication (SHAPE) submitted an NCD request (i.e.., "A Formal Request for a National Coverage Determination for Coronary Artery Calcium Testing") to CMS on January 7, 2019 that is currently in the review stage.
Formal submission of a Local Coverage Determination (LCD) request to regional Medicare contractor with jurisdictional authority over an assigned region	Medicare; regional in scope.	In the absence of a national coverage policy, an item or service may be covered at the discretion of the Medicare contractors based on an LCD. The processes and mechanism by which interested parties within a contractor's jurisdiction may request a new LCD or reconsideration request for an active LCD differs slightly from one contractor to the next. With that said, petitioners must adhere to the submission requirements and criteria established by both CMS and the contractor being petitioned. Several contractors have existing LCDs in effect pertaining to CAC scoring and, as far as the AHA is aware, no petitions have been filed by SHAPE or other stakeholders subsequent to the release of the 2018 ACC/AHA guidelines.

Petitioning the U.S. Preventative Services Task Force (USPSTF) to	Medicaid Medicare Private health plans	The USPSTF is an independent panel of experts in primary care and prevention who systematically reviews the evidence of effectiveness and develops recommendations for clinical preventive services. A key provision of the Affordable Care Act (ACA) is the requirement that private insurance plans cover services for adults that have a USPSTF rating of "A" or "B" without any patient cost-sharing. With the exception of "grandfathered" or "grandmothered' health plans, the preventative services rules apply to all private plans (i.e., individual, small group, large group and self-insured plans). Further, individuals participating in Medicare and the Medicaid expansion population (i.e., the new adult group) are required to be provided with access to preventive services without cost-sharing. Note that the USPSTF concluded in 2018 that the current evidence was insufficient to assess the balance of benefits and harms of CAC scoring to traditional risk assessment for cardiovascular disease (CVD) in asymptomatic adults to prevent CVD events.[4] With that said, the ACC/AHA guidelines released in November 2018, as well as the evidence considered in developing said guidelines, were not considered in that review.
Supporting the introduction and passage of state-specific benefit mandates	Variable; depends on the text of a bill, statute and/or regulations	As it currently stands, only Texas has an existing mandate related to the coverage of and payment for CAC tests. SHAPE is leading efforts for legislative mandates in several other states, including California and South Carolina, but none have yet succeeded to the point of legislative

[4] https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/cardiovascular-disease-screening-using-nontraditional-risk-assessment

		passage, being signed into law, and being codified into state statutes and implementing regulations. The primary limitation to state-specific benefit mandates is that the requirements apply only to plans subject to state statutes and regulations. While any bill signed into law in a specific state would likely apply to a large swath of fully insured coverage arrangements, self-funded plans would remain free to deny coverage/payment given longstanding ERISA pre-emption protections. Thus, state mandates would leave the largest source of insurance coverage (i.e., ERISA plans offered through self-funded employer arrangements) free to decide to what extent, if at all, CAC scoring would be covered and paid for.
Working directly with payors to advocate for inclusion in their benefits packages and/or groups that are contracted with or represent large cohorts of payors to encourage more widespread adoption	Variable; depends on the payor's scope of control and level of interest (e.g., single employer plan, all of an insurance company's individual market plans, blanket coverage across a payor's full suite of off-the-shelf, insured products)	The option exists to approach large employers with interests similar to the AHA to pilot the inclusion of CAC testing into their own health plans (e.g., health systems that offer the test to patients, but don't include it in their own employer-sponsored plans). Further, the AHA could work directly with technology assessment firms or organizations that are designed to speed the uptake of new guidelines or evidence into clinical practice (e.g., Evidence Street at the BlueCross BlueShield Association, National Guideline Clearinghouse (NGC) at the Agency on Healthcare Research and Quality (AHRQ)) to encourage a review of the new guidelines and explore ways for the recommended interventions considered in the ACC/AHA to be incorporated into payors' clinical and payment policies.

The Policy Research Department links scientists, clinicians and policymakers to improve cardiovascular health and decrease heart disease and stroke mortality. For more information, visit http://bit.ly/HEARTorg-policyresearch or connect with us on Twitter at @AmHeartAdvocacy using the hashtag #AHAPolicy.

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