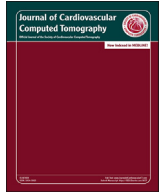




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Healthcare Policy Statement on the Utility of Coronary Computed Tomography for Evaluation of Cardiovascular Conditions and Preventive Healthcare: From the Health Policy Working Group of the Society of Cardiovascular Computed Tomography

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ABSTRACT

The rising cost of healthcare is prompting numerous policy and advocacy discussions regarding strategies for constraining growth and creating a more efficient and effective healthcare system. Cardiovascular imaging is central to the care of patients at risk of, and living with, heart disease. Estimates are that utilization of cardiovascular imaging exceeds 20 million studies per year.

The Society of Cardiovascular CT (SCCT), alongside Rush University Medical Center, and in collaboration with government agencies, regional payers, and industry healthcare experts met in November 2016 in Chicago, IL to evaluate obstacles and hurdles facing the cardiovascular imaging community and how they can contribute to efficacy while maintaining or even improving outcomes and quality. The summit incorporated inputs from payers, providers, and patients' perspectives, providing a platform for all voices to be heard, allowing for a constructive dialogue with potential solutions moving forward. This article outlines the proceedings from the summit, with a detailed review of past hurdles, current status, and potential solutions as we move forward in an ever-changing healthcare landscape.

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Recent estimates project spending for healthcare services to exceed \$3 trillion dollars in 2015.¹ The Centers for Disease Control and Prevention estimates that cardiovascular disease costs nearly \$1 billion dollars each day in healthcare costs and lost productivity.¹

The rising cost of healthcare is prompting numerous policy and advocacy discussions regarding strategies for constraining growth and creating a more efficient and effective healthcare system. Cardiovascular imaging is central to the care of patients at risk of, and living with, heart disease. Estimates are that utilization of cardiovascular imaging exceeds 20 million studies per year.

Over the last decade, there has been a substantial growth in evidence supporting the impact of cardiovascular computed

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Abbreviations

ACA	Affordable Care Act
AUC	Appropriate Use Criteria
ACC	American College of Cardiology
AHA	American Heart Association
APM	Alternative Payment Model
CAD	Coronary Artery Disease
CTA	Computed Tomography Angiography
CMS	Centers for Medicare and Medicaid Services
DoD	Department of Defense
ED	Emergency Department

EKG	Electrocardiogram
FFS	Fee-for-service
HTA	Healthcare Technology Assessments
PCE	Pooled Cohort Equation
NICE	National Institute for Health and Care Excellence
NHS	National Health Service
SCCT	Society of Cardiovascular Computed Tomography
SOC	Standard of Care
TA	Technology Assessment
US	United States
UK	United Kingdom

tomography (CCT) on patient management and important clinical outcomes. Large multicenter registries and randomized trials now support appropriate indications for the use of CCT in the evaluation and management of acute and stable ischemic heart disease, procedural planning for structural heart disease, and screening for subclinical atherosclerotic cardiovascular disease, to name a few. Noninvasive coronary CT angiography (coronary CTA) has a high degree of accuracy for diagnosing coronary artery disease (CAD), identifying a broad spectrum of atherosclerosis from minimal plaque to severe stenosis. In addition to its diagnostic capabilities, the prognostic implications of coronary CTA have been validated in several large randomized trials and multinational registries.^{2–7} In addition to identifying the severity and extent of CAD, coronary CTA can also identify high risk plaque features which are associated with a higher risk of future adverse coronary events and rehospitalization.^{8–10} In total, more than 10 large clinical trials have been reported comparing coronary CTA with functional testing approaches and invasive angiography. Data from these trials support that coronary CTA is equally effective and, in some cases, superior to functional testing with regards to patient outcomes. In addition, some trials have shown that coronary CTA leads to a greater improvement in angina¹¹ without added costs. However, the utilization and growth of coronary CTA remains suboptimal relative to the evidence for clinical efficiency compared to other imaging modalities.

1. Society of Cardiovascular Computed Tomography (SCCT) Healthcare Policy Summit: from vision to reality

Our healthcare system is evolving rapidly, resulting in many challenges for clinicians and imagers seeking to provide patient-focused care strategies centered on the appropriate use of high-quality, efficient, diagnostic testing. The goal of the SCCT is to provide practical assistance and guidance, to bridge the existing gap between the lagging healthcare coverage policies and current multi-society appropriate use criteria (AUC), working towards effective referral patterns and utilization of CCT. SCCT seeks to provide support and guidance for clinicians, healthcare provider networks, and payers, as well as to provide a voice for our patients who may benefit from the adoption of innovations in CCT.

The members of the health policy committee at the SCCT brought together experts in the field of health policy from health plans, specialty benefits managers, and advocacy experts from the American College of Radiology (ACR), American College of Cardiology (ACC), and the Medical Imaging and Technology Alliance for a dedicated health policy summit to discuss the state of the evidence for CCT and strategic policy initiatives focused toward effective, efficient, and appropriate utilization of CCT. The purpose of this

SCCT Policy Summit was to broadly engage in partnerships with all stakeholders toward a utilization platform for CCT that embraces the concepts of patient-centered and value-based imaging. This policy summit was held in partnership with Rush University Medical Center (RUMC), multiple industry leading partners, the Department of Veteran's Affairs (VA), and the Office of the United States Army Surgeon General (Army OTSG). From November 4–5th 2016, this pool of experts reviewed and discussed the clinical effectiveness and economic evidence for CCT, including coronary artery calcium scoring (CACS). The summit targeted discussions within the context of state-of-the-art best evidence, guideline-directed testing, and the ACR's Appropriateness or ACC's Appropriate Use Criteria (AUC). Throughout this paper, we will highlight clinical evidence and financial implications of coronary CTA use, as reflected in the discussions amongst all stakeholders in this summit.

2. How science is integrated into payer coverage policies? – translating experimental technology into the standard of care (SOC)

Multiple models and criteria are used by private payers in the evaluation of emerging technologies to evaluate evidence supporting medical coverage. The standards for meeting medical necessity vary widely by payer and cause considerable confusion for both physicians and patients. To improve understanding of the process of technology assessment, we highlight a set of coverage criteria utilized by one of the major healthcare coverage entities, shared with SCCT during the 2016 Healthcare Policy Summit.

2.1. Technology assessment (TA) process

The TA process is applied to both the development of new policies and review of existing policies for medical necessity. Initially, literature searches are conducted with rigorous evaluation of the quality of the peer-reviewed scientific evidence for each reviewed technology. Systematic reviews are then submitted to a review group for analysis based on established criteria to determine if the evidence supports coverage. In most cases, a failure to meet criteria will result in a technology classified as investigational. As an example, the major criteria for coverage employed by Blue Cross Blue Shield Medical Technology Assessment Guidelines is listed in [Table 5](#), and utilized in this section.¹²

The methodology applied for a technology to transition from investigational to accepted SOC is based on rigorous evidence of scientific results. As an initial statement, coronary CTA has United States (US) and International regulatory approval to be used in its current capacity both as a diagnostic and prognostic tool.^{13–21} The

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