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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

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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

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

TA process, however, disadvantages new technology, as it is a lengthy process which delays patient access to the benefits, and delays the efficiencies to the providers, of recent advances in imaging. For the most part, the TA process is independent and not influenced by recommendations from medical society clinical practice guidelines or AUC. For this document, we present a brief synopsis of controlled clinical and randomized trials that provide fulfillment of the above TA criteria. This summary synthesizes the scientific evidence on the: a) diagnostic accuracy of coronary CTA as compared to invasive coronary angiography (ICA), b) comparative effectiveness of coronary CTA to accepted SOC testing, and c) health economics data identifying comparative efficiency and savings associated with coronary CTA-guided clinical management. We break down the available trial evidence into the following sections:

1. Controlled clinical trials of the diagnostic accuracy of coronary CTA as compared to ICA and stress imaging modalities:
 - a) **ACCURACY²² Trial** - A controlled clinical trial of 230 patients with stable chest pain who underwent coronary CTA and ICA. The diagnostic sensitivity and specificity was 95% and 83%, respectively.
 - b) **Meijboom²³ Trial** - A controlled clinical trial of 360 symptomatic patients who underwent coronary CTA and ICA. The diagnostic sensitivity and specificity was 99% and 64%, respectively.
 - c) **CORE 64²⁴ Trial** - A controlled clinical trial of 291 patients with stable chest pain who underwent coronary CTA and ICA. The diagnostic sensitivity and specificity was 85% and 90%, respectively.
 - d) **EVINCI Trial²⁵** - A controlled clinical trial of 475 patients who underwent coronary CTA, stress testing, and ICA. Coronary CTA had a diagnostic sensitivity and specificity of 90% and 93%, respectively which was higher than for stress myocardial positron emission tomography (PET) or single-photon emission computed tomography (SPECT), echocardiography, or magnetic resonance imaging (MRI).
 - e) **PICTURE Trial²⁶** - A controlled clinical trial of 230 patients who underwent stress myocardial perfusion SPECT and coronary CTA as well as ICA. Coronary CTA had a diagnostic sensitivity and specificity of 92% and 87%, respectively. Stress myocardial perfusion SPECT had a lower sensitivity and specificity of 55% and 78%, respectively.
2. Is coronary CTA equivalent to the established SOC for evaluation of stable and acute chest pain with a net health benefit to the patient, in a way achievable outside the investigational setting?
 - a) **CAPP Trial²⁷** - A randomized trial of 488 symptomatic patients allocated to a strategy of coronary CTA versus exercise testing. At 3-months and at 1-year, patients randomized to coronary CTA had an improvement in angina stability and overall quality of life as compared to exercise testing.
 - b) **PROMISE Trial²⁸** - A randomized trial of 10,003 symptomatic but stable patients allocated to a functional strategy (67% stress nuclear, 23% stress echocardiography, and 10% exercise electrocardiography) compared to coronary CTA. At 3 years, the primary outcome, a composite of major cardiovascular events, was similar for CTA and the functional strategies (3.3% vs. 3.0%; $p = 0.75$). Similar 3-year healthcare costs were reported for functional testing versus coronary CTA in the PROMISE trial.²⁹
 - c) **SCOT-HEART Trial³⁰** - A randomized trial of 4146 symptomatic but stable patients allocated to the SOC testing (with 85% of patients undergoing exercise testing) as compared to coronary CTA. At 3-year, coronary heart disease death and myocardial infarction (MI) rates were numerically lower and demonstrated a trend towards significance for CTA (1.3% compared to standard of care (2.0%; HR 0.62; $p = 0.053$). A landmark analysis of the impact of therapy initiated, on outcomes in the coronary CTA arm, revealed that starting at 50 days post initiation of therapy, the rates of fatal MI, non-fatal MI, as well as strokes were reduced by 50% as compared to SOC ($p = 0.02$).⁵
 - d) **Dewey Trial³¹** - A randomized trial of 340 symptomatic but stable patients allocated to direct ICA compared to coronary CTA. At 3-years, major cardiovascular outcomes were similar (ICA 3.7%, coronary CTA 4.2%; $p = 0.86$).
 - e) **Clinical Outcomes After Evaluation of Stable Chest Pain by coronary CTA Versus Usual Care: A Meta-Analysis.³²** A systematic review of randomized clinical trials comparing coronary CTA (7403 patients) with SOC (7414 patients) for the evaluation of stable chest pain, evaluating cardiovascular outcomes. Coronary CTA was associated with a lower annual MI rate compared to SOC (odds ratio, 0.69; 95% confidence interval, 0.49–0.98; $P = 0.038$).
 - f) **ACRIN-PA Trial³³** - A randomized trial of 1370 patients presenting to the Emergency Department with a low risk TIMI score (0–2) allocated to traditional care compared to coronary CTA. The primary outcome of safe discharge following a negative examination occurred in 50% of coronary CTA and 23% of traditional care patients. In addition, compared to traditional care, coronary CTA was associated with a higher rate of discharge from the Emergency Department and shorter length of stay ($p < 0.001$). Coronary CTA had a higher rate of detection of CAD as compared to traditional care. Following a negative coronary CTA ($n = 640$), no patient died or had an acute MI.
 - g) **ROMICAT II Trial³⁴** - A randomized trial of 1000 acute chest pain patients without ischemic electrocardiographic changes and no Troponin elevations allocated to a standard evaluation or coronary CTA. The primary endpoint was length of stay which was reduced by 7.6 h with coronary CTA compared to the SOC arm ($p < 0.0001$). No significant differences in major adverse cardiovascular events were reported at 28 days of follow-up.
 - h) **CT-STAT Trial^{35,36}** - A randomized trial of 699 patients with a TIMI risk score ≤ 4 and without biomarker elevation allocated to index myocardial perfusion imaging compared to coronary CTA. The primary outcome of time to diagnosis was 54% shorter for coronary CTA (i.e., median of ~3 h) when compared to myocardial perfusion imaging ($p < 0.001$). There were no differences in major adverse cardiovascular events following a negative study ($p = 0.29$).
 - i) **Clinical outcomes after coronary CTA in the Emergency Department: A systematic review and meta-analysis of randomized controlled trials** – Among 1869 patients undergoing coronary CTA and 1391 undergoing usual care, coronary CTA was associated with decreased Emergency Department costs and length of stay but increased ICA and revascularization.³⁷
 - j) **Evidence from Multicenter Registries – Example from the Coronary CTA Evaluation For Clinical Outcomes: An International Multicenter (CONFIRM) Registry** - The CONFIRM dynamic registry enrolled over 20,000 consecutively tested patients from 12 sites. All patients underwent coronary CTA and were prospectively followed for 5 years with data collected on major adverse clinical outcomes.^{4,6,38–40} We highlight selected publications^{4,6,38–40} as the CONFIRM registry has published over 30 peer-reviewed manuscripts since 2011 and highlights the “real world” predictive accuracy of coronary CTA in the evaluation of stable ischemic heart disease. Coronary CTA has effective risk

stratification among younger and older patients, women and men, diabetics and non-diabetics, obese and non-obese, and among racially- and ethnically-diverse patients, to name a few.^{2,4,6,38,41–44} This section highlights the diversity of “real world” data with results similar to that published from randomized trials.^{7,45}

- k) **Technology Assessment in the United Kingdom (UK) – Guidance Documents from the National Institute for Health and Care Excellence (NICE)** - In the UK, NICE evaluates new technologies and has robust and rigorous criteria for evaluation of diagnostic imaging, such as coronary CTA. In 2010, NICE published guidance on the assessment of chest pain of recent onset.^{46,47} In patients with stable chest pain, and a pre-test likelihood of significant CAD of 10–29%, coronary artery calcium scoring (CACS) was recommended as a first line investigation, with those having a CACS of 1–400 recommended for subsequent coronary CTA. This shifted the initial investigation of stable chest pain patients away from exercise stress testing and was subsequently shown to be cost effective, despite the higher cost of the initial investigation.^{46,48,49} However, several studies suggested that the assessment of pretest likelihood both over-estimated the population burden of disease⁵⁰ and failed to identify “at risk” patients, both with the pretest likelihood assessment and the exclusion of coronary CTA in patients with a CACS of zero.^{46,51}

In 2016, NICE updated its guidance on the investigation of stable chest pain²¹ and having re-evaluated the coronary CTA evidence, alongside the alternative imaging modalities, recommended coronary CTA as the first line investigation in all patients with typical or atypical angina symptoms, or if asymptomatic with electrocardiogram (EKG) changes suggestive of ischemic heart disease (IHD), regardless of pre-test likelihood of significant CAD.^{46,52} NICE has calculated that the use of coronary CTA as a first line investigation will save the UK National Health Service (NHS) \$20 million annually by the exclusion of significant CAD and by restricting more costly functional imaging to those with proven CAD commensurate with anginal symptoms.

3. Clinical practice guidelines and appropriate use criteria (AUC) involving coronary CTA

We highlight published AUCs and guidelines for CACS and coronary CTA (indications for evaluation of stable and acute chest pain).

3.1. Preventive screening

Several guidelines are available to guide the use of CACS, and a review of all the extensive evidence in this field is beyond the scope of the current document.⁵³ A recent statement from SCCT and from the Society of Thoracic Radiology⁵³ (Table 1), provides a summary of clinical indications for CACS on non-gated scans used in low dose lung screening and all non-contrast CTs for CACS.⁵³ In the 2013 American College of Cardiology (ACC)/American Heart Association (AHA) Guideline on the Assessment of Cardiovascular Risk,⁵⁴ CACS was supported as the “most useful of the current approaches to improving risk assessment among individuals found to be at intermediate risk after formal risk assessment.” The ACC/AHA clinical practice guidelines have assigned CACS a class IIa or IIb level of evidence.^{54–57} Current evidence suggests that there is considerable overestimation of risk by the PCE, and subsequently a sizeable proportion of individuals who are candidates for statin therapy have no evidence of coronary atherosclerosis. Specifically, investigators from the MESA study have found that nearly half of

individuals who meet the criteria for statins based on the 2013 ACC/AHA guidelines have no evidence of atherosclerosis by CACS, and a very low event rate over the next 10 years of follow-up.⁵⁸ Consequently, in the context of shared decision making, the use of CAC scoring could be used to provide a more precise estimate of risk, and is particularly useful among individuals who are 40–75 years of age and have a 5–20% 10-years ASCVD risk. In such individuals, a CAC score of zero, which would be found in up to half of individuals, would reclassify them to a sufficiently low risk that statin use could be deferred, while focusing on lifestyle interventions.

3.2. Evaluation of stable but suspected cardiac symptoms (Table 2)

The evaluation of chest pain or suspected cardiac symptoms has been covered by several ACC documents including the evaluation of Stable Ischemic Heart Disease¹⁴ and Multimodality AUC for Detection and Risk Assessment.¹³ Table 2 details the 2013 indications for coronary CTA based on these ACC documents. The indications are robust and support utilization of coronary CTA in the evaluation of stable chest pain. As many as half of stable chest pain patients have persistent symptoms without documentation of myocardial ischemia.^{18,59–61} The randomized trial evidence supports the equivalent or improved effectiveness of coronary CTA as a frontline procedure. Pooling the data from the randomized trials further reveals that coronary CTA improves the certainty of diagnosing angina by identifying the extent and severity of CAD,^{22–24} has a higher rate of detecting obstructive CAD,^{11,28,30} and results in appropriate downstream utilization of anti-ischemic and preventive therapies.^{5,62} Importantly, from the ACC's CathPCI registry of 376,430 patients undergoing diagnostic ICA following stress testing, only 41% had obstructive CAD.⁶³ The pooled randomized trial data reveal that the rate of detecting obstructive CAD by coronary CTA improves to 71% as compared to 52.5% for stress testing.^{11,28,30} Importantly, the higher CAD detection rate for coronary CTA occurs without a higher adverse cardiac event rate or untoward financial consequences over 3 years of follow up.²⁹ However, coronary CTA did result in higher invasive angiography and revascularization rates but without improvement in cardiovascular outcomes in PROMISE,²⁸ a primarily North American population, but trended toward better outcomes in the SCOT HEART⁶⁴ trial in the United Kingdom.

3.3. Evaluation of acute but low risk chest pain in the emergency department (Table 3)

Abundant data are available regarding the use of coronary CTA in the Emergency Department for the evaluation and diagnosis of patients with low-to-intermediate risk acute chest pain. In a meta-analysis of multiple large-scale randomized controlled trials, the use of early coronary CTA in low-to-intermediate risk patients presenting to the ED with recent onset chest pain was safe, highly accurate for the detection of acute coronary syndrome (ACS) and associated with improvements in numerous important healthcare outcomes, including significant reductions in length of stay, hospital admissions and time to diagnosis.⁶⁵ Importantly, all studies excluded patients with a prior diagnosis of coronary heart disease and those at high clinical likelihood for ACS (e.g., TIMI score >4 or dynamic ST changes) or with overt Non-ST-elevation MI (NSTEMI).

Prior to the publication of multiple randomized controlled trials assessing coronary CTA in the emergency department, the 2010 multi-societal guidelines considered coronary CTA as “Uncertain” for use in patients with low-to-intermediate risk acute chest pain.⁶⁶ However, based on the data highlighted above, multiple societies, including the SCCT, ACC, American College of Radiology (ACR) and AHA, recently published the 2015 Appropriate Utilization of

Table 1
2017 Calcium score appropriate use criteria.

B. Coronary Artery Calcium Guidelines	Population	Recommendation
2009 USPSTF (29)	NA	C
2010 ACC/AHA Risk Guidelines (11)	10–20% intermediate risk	IIa
	Diabetics >40 year-old	IIa
	6–10% low to intermediate risk	IIb
2010 Appropriate Use Criteria (30)	10–20% intermediate risk	Appropriate
	Low risk with family history of premature coronary disease	Appropriate
	High risk	Uncertain
	Low risk	Inappropriate
2013 ACC/AHA Cholesterol and Risk Guidelines (4, 31)	Uncertain risk after Pooled Cohort Equations	IIb
2016 ESC Cardiovascular (4) Disease Prevention Guideline	Approx. 5% or 10% SCORE threshold	May be

*Reprinted in part with permission of H.S. Hecht et al./Journal of Cardiovascular Computed Tomography 11 (2017) 74e84. ACC = American College of Cardiology, AHA = American Heart Association, ESC = European Society of Cardiology, SCORE = Systematic COronary Risk Evaluation, USPSTF= **United States Preventive Services Task Force**. Recommendation C = Clinicians may provide this service to selected patients depending on individual circumstances. However, for most individuals without signs or symptoms there is likely to be only a small benefit from this service. Recommendation IIa = Weight of evidence/opinion is in favor of usefulness/efficacy. Recommendation IIb = Usefulness/efficacy is less well established by evidence/opinion.

Imaging in Emergency Room Patients with Chest Pain.⁶⁷ In this document, coronary CTA was one of only 2 tests (the other was SPECT during active chest pain) graded as “Appropriate” for the early assessment of patients with an initial negative troponin assay presenting to the Emergency Department without clear NSTEMI or at high risk for ACS. While the use of hs-troponin assays may reduce the need for any testing in the low risk patients with clearly undetectable hs-troponin levels, many patients will be left with detectable hs-troponin values unrelated to ACS.^{68,69} In these cases, coronary CTA is an efficient test to more definitively rule-out ACS in such patients.

SPECT testing performed within hours of chest pain showed high sensitivity for ACS, but this has been largely abandoned worldwide due to expense and limited technician availability out of usual office hours. Recently, to ensure high-quality, low-radiation performance of coronary CTA in the Emergency Department, the SCCT published a guideline focused on ensuring consistent imaging quality and safety of coronary CTA in the Emergency Department.⁷⁰

4. Evidence supporting coronary CTA use in special populations - guideline applications in the military, veterans, and high occupational risk

The US DoD, like most military organizations, does not employ a screening tool for accurate prediction of future cardiovascular event risk. Global risk scores, such as the PCE, are largely based on age and significantly underestimate risk in younger patient subgroups⁶² and fail to identify the risk of events in high risk populations as evident in the recent evaluation of sudden cardiac death data in active duty personnel over 35 years of age.⁵⁷ Fatality data (per

person-year) in combat is 21/100,000, while the sudden cardiac death fatality rate in those 45–49 years of age is 44/100,000, and is 112/100,000 in the >50 age group despite the military cardiovascular prevention programs.⁷¹ In 1988, the Armed Forces Epidemiological Board (AFEB) found that the Army Cardiovascular Screening Program had no meaningful impact on the incidence of death due to CAD, since more than half of the events occurred in those in the ‘low-risk’ group (Armed Forces Epidemiological Board 1988;(15-1a):88-1). UK data also demonstrate that the prevalence of death from CAD was higher than expected.⁷² Other predictive models were tried in the past, as evident in the Prospective Army Coronary Calcium (PACC) trial^{73,74} and found that in those over >40 years of age, the identification of CAC was associated with a 12-fold increase in cardiovascular events compared to conventional risk. Not only did CAC predict outcomes more accurately, it improved compliance with preventive therapy and lifestyle recommendations^{73–77}

When assessing young military personnel at low-intermediate risk with high risk occupations, coronary CTA has been shown to significantly lower false positive results and subsequent ICA when compared to exercise nuclear stress testing.⁷⁸ Furthermore, coronary CTA had an accepted warranty period of at least 24 months with no cardiovascular events in patients without obstructive CAD,⁷⁹ as well as much lower incidence of re-evaluation for recurrent chest pain when compared to accepted modalities for chest pain evaluation.⁸⁰ coronary CTA has been evaluated in two major military medical centers, with data supporting its negative predictive value, long term warranty, extremely low radiation dose exposure, and overall significant cost saving to the government with little to no impact on mission operations or performance.^{62–66}

Table 2
ACC/AHA appropriate use criteria for coronary CT.

Indication	2013 ACC/AHA Appropriate Use Criteria
Chest pain with intermediate pretest probability of CAD with ECG uninterpretable OR unable to exercise	A
Recurrent Chest pain with abnormal Treadmill testing within 90 days	A
Recurrent Chest pain with abnormal stress imaging within 90 days	A
Recurrent Chest pain with non diagnostic Treadmill testing within 90 days	A
Recurrent chest pain with non diagnostic stress imaging within 90 days	A
New or worsening chest pain with normal Treadmill testing	A
New or worsening Chest pain with abnormal Treadmill testing	A
New or worsening chest pain with abnormal stress imaging	A
New systolic heart failure	A

Appropriate use key: A = appropriate; ACC = American College of Cardiology, AHA = American Heart Association, CAD= Coronary artery disease; coronary CTA, coronary CT angiography; ECG, electrocardiography.

*Wolk MJ, et al. ACCF/AHA/ASE/ASNC/HFSA/HRS/SCAI/SCCT/SCMR/STS 2013 multimodality appropriate use criteria for the detection and risk assessment of stable ischemic heart disease. J Am Coll Cardiol. 2014; 63(4):380-406.

Table 3
2015 appropriate use criteria for acute chest pain in the emergency department.

Indication	Coronary CTA
Equivocal initial diagnosis of NSTEMI/ACS	
1. Equivocal initial troponin or single troponin elevation without additional evidence of ACS	A
2. Ischemic symptoms resolved hours before testing	A
Low/intermediate likelihood initial diagnosis of NSTEMI/ACS	
3. TIMI risk score = 0, early hsTrop negative	A
4. Normal or non-ischemic on initial ECG, normal initial troponin	A
5. Diagnosis unequivocally positive for NSTEMI/ACS	M
6. Serial ECG and troponins negative for NSTEMI/ACS	A
7. Serial ECG or troponins borderline for NSTEMI/ACS	A

Appropriate use key: A = appropriate; M = Maybe Appropriate; ACS, acute coronary syndrome; coronary CTA, coronary CT angiography; ECG, electrocardiography; hsTrop, high-sensitivity troponin T; NSTEMI, non-ST-segment elevation myocardial infarction; TIMI, Thrombolysis in Myocardial Infarction.

Rybicki F, et al. Appropriate Utilization of Cardiovascular Imaging. *J Am Coll Cardiol.* 2016; 67(7):853–879.⁶⁸

This is important to the military population in a constant state of deployment to global theater of operations, where not only is the cost of evacuation of symptomatic individuals extremely high, but it is also extremely detrimental to the mission's in currently lean operational force. The investigation of coronary CTA in military aircrew has also demonstrated the value of coronary CTA over CACS⁸¹ and this is likely to be highly relevant to civil aviation and others at high occupational risk, such as the transport industry and emergency services.

5. Economic evidence comparing coronary CTA with comparative diagnostic imaging modalities

A challenge and concern for cardiovascular imaging has been the high rates of utilization that has not been supported by abundant clinical trial and large registry data.⁸² Along with the comparative effectiveness evidence, abundant data are available with regards to the cost efficiency of coronary CTA. The optimal imaging guided strategy is one of the highest quality evidence demonstrating clinical effectiveness but at similar or reduced costs for a given strategy of care (i.e., the concept of value-based imaging). Table 4 reports Medicare reimbursement rates for 2017 for CACS and coronary CTA compared to other diagnostic imaging modalities, with selected procedural codes.

An important consideration that is integral to understanding test costs is not only the upfront considerations but induced testing patterns (i.e., cost consequences of a given test-driven strategy).⁸³ Several reports, including recent randomized trials and large multicenter registries, have examined follow-up testing patterns after index coronary CTA.^{15,29,34,36,39,84,85}

In the Emergency Department setting of acute but low risk chest pain, the UK's NICE evaluated the economic evidence of coronary CTA.¹⁵ Synthesis of this evidence revealed that the time to diagnosis using coronary CTA was reduced by 44–77% (or by 7.7 h) when compared to stress testing or other diagnostic testing modalities. Moreover, the use of coronary CTA in the Emergency Department for low risk chest pain was associated with a cost savings of \$680. In a secondary analysis from the ROMICAT II trial, use of coronary CTA in the Emergency Department was cost effective in patient subgroups with a prevalence of CAD <30%.⁸⁶ In summary, the NICE guidance document reported that the use of coronary CTA in the Emergency Department is a cost-effective strategy for troponin negative patients.¹⁵

A review of the evidence on the evaluation of stable chest pain identifies several unique cost consequences that provide insight into how coronary CTA is used to manage patients.^{5,69,87–89} For the comparator of stress testing, a large, multicenter registry⁹⁰ and randomized trial⁶⁰ have shown that stress myocardial perfusion

SPECT is associated with minimal changes or intensification of preventive therapies following index testing. However, observational evidence now supported by randomized trial data support a much greater utilization of guideline-directed medical therapy following index coronary CTA.^{5,69,87–89} One example of this is from the SCOT-HEART trial, where Williams and colleagues⁵ reported that coronary CTA was associated with a nearly 4- and 12-fold increased utilization of statin and antiplatelet therapy, respectively. In landmark analysis, where time 0 was begun at the follow-up office visit (i.e., ~50 days post-randomization), there was an observed 50% reduction in acute MI for coronary CTA as compared to the SOC strategy.⁵ This data helped inform expected costs of care, especially related to the use of downstream cardiovascular medications.

In related observational analyses, coronary CTA increased the rate of downstream ICA.^{39,84} However, the randomized trial data supported a higher, near-term use of ICA following index coronary CTA but with several additional findings. First, the increased use of ICA was largely in the first 3 months of follow-up and resulted in a reduced use of ICA in the long-term, as compared to functional testing, as reported in the PROMISE trial.²⁹ Secondly, of those selected to undergo ICA, the rate of detection of CAD was much greater for coronary CTA (72%) compared to functional testing (52.5%), in a pooled analysis from the PROMISE, SCOT-HEART, and CRESCENT trials.^{11,28,30} These findings suggest that the near-term slightly greater use of ICA following coronary CTA improves the detection of those with revascularizable CAD and significantly reduces the rate of normal (unnecessary) ICA following non-invasive testing.

Although decision analytic models have been published,^{91–96} we will focus on recent randomized trial evidence for analyses with “real world” cost findings compared to functional testing.²⁹ From the PROMISE trial, detailed analysis of collected cost data were available in 9649 randomized patients.²⁹ These results revealed no differences in costs of care at 3 months through 3-years of follow-up; findings were similar for stress EKG, stress echocardiography, and nuclear imaging compared to coronary CTA. Similarly, in the SCOT-HEART trial, cumulative 6-month costs were slightly higher for coronary CTA but overall differences in costs were not statistically different from the SOC arm of the trial.⁵

A 16% cost savings was reported in the CRESCENT trial when CACS was used as the index testing followed by selective coronary CTA for those with detectable CAC as compared to exercise testing.¹¹ In the exercise testing arm of the CRESCENT trial there was a sizeable proportion of patients with follow-up stress testing within 1-year of follow-up; similar to the observations of repeat stress testing in the PROMISE trial.²⁹ For stress EKG, follow-up stress imaging is common among patients with indeterminate or

Table 4
2017 Final medicare physician fee schedule rule and 2017 final hospital outpatient prospective payment system rule.

Current Procedural Terminology (CPT) Codes	MPPFS Professional Component (PC) and Technical Component (TC) Payment 2017	OPPS TC Payment 2017
75571 CT heart w/out contrast, with quantitative evaluation of coronary calcium	\$102.28 TC = \$72.85 PC = \$29.43	\$59.84 APC 5521
75572 CT heart w/contrast for evaluation of cardiac structure and morphology	\$287.47 TC = \$198.82 PC = \$88.65	\$264.90 APC 5571
75573 CT heart w/contrast for evaluation of cardiac structure and morphology (congenital heart disease)	\$395.85 TC = \$266.64 PC = \$129.21	\$264.90 APC 5571
75574 CT angiography heart, coronary arteries and bypass grafts w/contrast	\$426.72 TC = \$305.41 PC = \$121.31	\$264.90 APC 5571
75557 Cardiac MR imaging for structure and morphology w/out contrast	\$324.43 TC = \$206.00 PC = \$118.43	\$225.81 APC 5523
75559 Cardiac MR imaging for structure and morphology w/out contrast with stress imaging	\$443.23 TC = \$297.16 PC = \$145.46	\$225.81 APC 5523
75561 Cardiac MR imaging for structure and morphology w/out contrast, followed by contrast, and further sequences	\$430.66 TC = \$299.67 PC = \$130.99	\$426.34 APC 5572
75563 Cardiac MR imaging for structure and morphology w/out contrast, followed by contrast, and further sequences, with stress imaging	\$513.21 TC = \$363.19 PC = \$150.02	\$656.63 APC 5573
93350 Echocardiography rest and cardiovascular stress test w/interpretation and report	\$243.47 TC = \$174.14 PC = \$72.32	\$449.50 APC 5524
93351 Echocardiography rest and cardiovascular stress test w/interpretation and report including electrocardiographic monitoring with physician supervision	\$273.90 TC = \$187.61 PC = \$86.29	\$449.50 APC 5524
78452 Myocardial perfusion imaging, tomographic (SPECT) (including attenuation correction, qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection	\$494.56 TC = 414.17 PC = \$80.39	\$1138.46 APC 5593
78453 Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); single study, at rest or stress (exercise or pharmacologic)	\$318.34 TC = \$267.74 PC = \$50.60	\$1138.46 APC 5593
78454 Myocardial perfusion imaging, planar (including qualitative or quantitative wall motion, ejection fraction by first pass or gated technique, additional quantification, when performed); multiple studies, at rest and/or stress (exercise or pharmacologic) and/or redistribution and/or rest reinjection	\$457.96 TC = \$389.77 PC = \$68.19	\$1138.46 APC 5593

OPPS, Outpatient Prospective Payment System; APC, Ambulatory Payment Classification; CT, computed tomography; MR, magnetic resonance; SPECT, Single Photon Emission Computed Tomography; MPPFS, Medicare Physician Fee Schedule.

Table 5
Blue cross blue shield medical technology assessment guidelines.

The technology must have final approval from the appropriate government regulatory bodies.
The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
The technology must improve the net health outcome.
The technology must be as beneficial as any established alternatives.
The improvement must be attainable outside the investigational settings

positive findings.¹⁴ These data suggest that a CACS may be an effective gatekeeper for the use of diagnostic testing in the evaluation of stable chest pain patients.

6. Saving models: viability in “Fee for service” or “Alternate payment” models

Fee-for-service (FFS) is still the predominant payment model in the US, but there has been a significant increase in the use of ‘value-based’ or ‘alternative payment’ models (APM) over the past decade. Recognizing that FFS models pay providers based on the quantity, rather than quality, of care, using incentives to improve care and linking payment to value through new payment models are some of the core components that The Centers for Medicare and Medicaid

Services (CMS) has linked to its quality strategy. To that end, CMS has committed to aggressive goals to attribute the majority of payments to APMs by 2018.^{97,98}

Reimbursements within the FFS construct make it difficult to change existing SOC in favor of improved pathways or a new technology if the reimbursement fails to appropriately capture the value of the change. This is one possible explanation for the lack of broad adoption of CCT technologies in certain settings. Despite CMS being the largest single payer, there are hundreds of other private payers that set their own coverage and payment policies for new technologies. “Making operational changes will be viable and attractive only if new APM and payment reforms are broadly adopted by a critical mass of payers. When providers encounter new payment strategies for one payer but not others, the incentives

to change are weak. When payers align their efforts, the incentives to change are stronger and the obstacles to change are reduced.”^{99,100}

A broader issue within the FFS payment environment which is pertinent to CCT is the lack of care coordination, value capture of the services provided and indirect downstream costs over an entire episode of patient care. Many of the applications of CCT accrue benefits long after the initial diagnostic service. FFS payment models fail to capture these benefits, possibly introducing perverse dis-incentives (or at least not making attractive) the appropriate use of CCT, thereby increasing patient costs and decreasing care patient quality in the long run, when best options are not utilized.^{101,102}

7. Appropriateness and applicability of APMs in the context of CCT

APM models fall into several distinct categories: quality linked FFS reimbursements, bundled (or episode of care) payments, and capitation, or population health management. FFS quality linked payments are still FFS reimbursements, a single payment for a single service, but that payment becomes conditional on the healthcare provider meeting certain pre-determined quality metrics. In bundled payment models, providers are paid for the care of a patient's medical condition across the entire care cycle—that is, all the services, procedures, tests, drugs, and devices used to treat a patient with, e.g., heart failure, an arthritic hip (that may need replacement), or diabetes.¹⁰³ These episode of care payments are structured around a patient's total experience of care, quality and cost, both in and out of the hospital. In capitation, health care organizations or providers receive a fixed payment per year, per covered life, to meet all the needs of that patient and all the needs of the broader patient population.

Of the three APM model types, bundled payments are the most ideal to drive appropriate use and applicability of CCT. That is because bundled payments are primarily focused on the acute care space and are intended to reduce cost and quality variations among episodes of care. Research has shown that bundled payments can support providers (hospitals, physicians, post-acute care personnel, and other clinicians) in working closely together to provide better care at lower cost.¹⁰⁴ Bundled payments, when working properly, incentivize standardization of care because the quality-adjusted target price should reflect the average cost and outcomes for episodes of care. Therefore, successful bundled payment providers provide the best possible care at the most efficient price, which is typically incentivized by bonus payments (or shared savings). Inefficient providers are driven to standards of care that their peers provide to ultimately avoid bundled payment financial penalties. So, if there are more efficient SOC for certain episodes that produce better outcomes at less cost, then bundled payment incentives should drive adoption of that certain care pathway. A properly structured bundled payment program could drive adoption of CCT

for certain episodes (e.g. chest pain in the Emergency Department).

CMS recognizes the savings potential associated with APMs, specifically with bundled payments, in cardiac care. That is clear from the focus on and design of three new bundled payment models as they will support clinicians in providing care to patients who receive treatment for heart attacks, heart surgery to bypass blocked coronary arteries, or cardiac rehabilitation following a heart attack or heart surgery.” As bundled payments are set to become one of the primary mechanisms for CMS to address cardiac care in the future, there remains ample opportunity in these early stages to apply learnings and outcomes from the SCCT to improve adoption of CCT.¹⁰⁵

8. Impacting change through legislative mandates to promote patient-centered preventive screening

Our healthcare system is undergoing a refocusing on value-based care and expanded coverage for those under- or uninsured, including the recent Affordable Care Act (ACA). A focus on value-based care examines quality within the setting of definable efficiencies and cost savings as well as a focus on early detection and screening to avert costlier downstream care. There are examples of state legislation which also focus on early detection of subclinical atherosclerosis, such as the 2009 “Texas Heart Attack Prevention Bill (HB1290)”. This bill mandated that all health plans pay for cardiovascular screening (every 5 years) for men >45 years of age and women >55 years of age.

Historically, national coverage policies for screening have been based on the US Preventive Services Taskforce (USPSTF); regulatory guidance within the ACA has altered this to mandate coverage by private payers, without copay, for recommended screening. The preventive services relevant to cardiovascular services covered under ACA at no charge to patients (Table 6)¹⁰⁶

All the above examples provide opportunities for detection of at-risk individuals. Following the observed marked reduction in mortality associated with lung cancer screening,¹⁰⁷ there is now a USPSTF recommendation for annual screening for lung cancer with low dose CT in adults aged 55–80 years with a 30 pack-year smoking history who currently smoke or those who quit ≤15 years.¹⁰⁸ During this CT procedure, visualization and documentation of a CACS is part of the examination. As such, recent guidelines have been published by SCCT and the Society of Thoracic Radiology for CACS for patients undergoing lung cancer screening,⁵³ not only for the potential 7–10 million patients undergoing annual lung cancer screening, but also for the 7.1 million patients undergoing non-contrast chest CT for routine diagnostic purposes.⁴⁵ The potential for the benefits of prevention has been greatly expanded.

9. Summary statements on comprehensive cardiovascular CT to enhance patient-centered imaging

Coronary CTA is no longer just a remarkable means of

Table 6

US Preventive Services Taskforce (USPSTF) recommended preventive services relevant to cardiovascular services covered under ACA at no charge to patients.

Abdominal aortic aneurysm one-time screening for men of specified ages who have ever smoked.
Aspirin use to prevent cardiovascular disease for men and women of certain ages.
Blood pressure screening.
Cholesterol screening for adults of certain ages or at higher risk.
Depression screening.
Diabetes (Type 2) screening for adults with high blood pressure.
Diet counseling for adults at higher risk for chronic disease.
Lung cancer screening for adults 55–80 years of age at high risk for lung cancer (heavy smokers or those that have quit heavy smoking in the past 15 years).
Obesity screening and counseling.
Tobacco use screening for all adults and cessation interventions for tobacco users.

visualizing cardiovascular disease. The imaging community has supplemented the technical improvements in image quality and precision with abundant clinical research on comparative effectiveness. This review highlights many of the presentations and discussions held at the Health Policy Summit. SCCT is currently expanding its policy and advocacy focus to actively engage in discussions with payers and policy experts to provide appropriate coverage and reimbursement for cardiovascular CT. Fortunately, over the past years, robust coverage in many areas of the country have paved the way for appropriate and patient-centered use of cardiovascular CT. Nonetheless, we believe that the current evidence base is robust and warrants a reevaluation of cardiac CT's "investigational" status from some payers, to an appropriate and effective first line test in appropriate patients.

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