

Coronary Computed Tomographic Angiography Overview & Preliminary Key Questions

Overview

Coronary artery disease is the leading cause of death in the U.S. among both men and women. Because of its prevalence, and because morbidity and mortality can be reduced through life-style modifications and the use of several well-established treatments, the diagnosis of coronary artery disease has very significant health and health service utilization consequences.

For many years the most precise and definitive method for the evaluation and diagnosis of coronary artery disease has been invasive coronary angiography (ICA). Coronary computed tomographic angiography (CCTA) has recently evolved technically to the point where it is being used by many clinicians as a complement to or replacement for other non-invasive and minimally invasive methods of diagnosis, such as exercise stress testing and radio-nuclide scans. CCTA is also being used or being studied as a diagnostic test whose precision may allow “negative” CCTA test results to eliminate the need for more invasive, risky, and expensive ICA for many patients.

Despite the growing interest in CCTA, many uncertainties remain about its appropriate use. Evidence review bodies and insurers have arrived at different interpretations of the published evidence on the diagnostic accuracy of CCTA and its impact on health outcomes. While CCTA is covered by many local Medicare contractors, coverage for many diagnostic indications varies widely among private insurers. Uncertainty remains on many aspects of the evidence, including the following:

- 1) The diagnostic accuracy of CCTA relative to ICA and other possible comparator diagnostic tests
- 2) The impact on patient outcomes and health care utilization of alternative diagnostic algorithms that integrate CCTA in different ways into the diagnostic pathways for patients with suspected coronary artery disease, both in the general outpatient setting and in the Emergency Department
- 3) How to identify appropriate target populations for CCTA, based on level of risk and symptoms
- 4) The potential negative impact of increased radiation exposure of CCTA
- 5) The impact of incidental findings that trigger further evaluation
- 6) The potential impact of CCTA on the thresholds for clinician testing for coronary artery disease among the general population
- 7) The budget impact and cost-effectiveness of integrating CCTA into diagnostic pathways for patients with suspected coronary artery disease

Key Questions to Assist in Determining ICER Appraisal Scope

1. The ICER appraisal will evaluate evidence on the head-to-head diagnostic accuracy of CCTA and ICA. But clinical, coverage, and reimbursement decisions around the adoption of CCTA are likely to be driven by considerations of the impact of integrating CCTA alongside other tests in diagnostic pathways for various kinds of patients. What are the most salient diagnostic pathways that should be considered by the ICER appraisal? For instance, should the ICER review prioritize looking at CCTA as:
 - a. An outpatient test for symptomatic patients with chronic stable angina who have had other non-invasive tests for CAD?
 - b. An initial outpatient test for symptomatic patients with chronic stable angina who have not had other non-invasive tests for CAD?
 - c. An Emergency Department test for patients presenting with acute chest pain of undetermined origin?
2. Assuming that prior probability of CAD is an important consideration in evaluating the usefulness of CCTA, what is the best way to incorporate “risk” into designing diagnostic pathways to be evaluated in the ICER appraisal? Should Framingham, Diamond-Forrester, or other risk stratification tools be used to specify definitions for “low,” “intermediate” and “high” risk?
3. In addition to CAD detection rates and associated survival, what are key patient outcomes and utilities the ICER appraisal should not overlook in evaluating the impact of integrating CCTA into care?
 - a. Adverse effects of false positive CCTA
 - b. Potential for increased risk of secondary malignancy from radiation exposure
 - c. Impact of incidental findings
 - d. Risks of invasive angiography
 - e. Value of reduction of uncertainty to patient well-being and future care
4. Are there any issues related to the recent technical evolution of CCTA or standards for interpreter training that the assessment should be aware of in terms of how to judge the applicability of published literature to current practice?
5. Are there any important issues about the validity or applicability of particular articles in the existing published data that the assessment should take into consideration?

6. Are there any existing guidelines (e.g., radiology management programs) or prior authorization criteria for CCTA that the assessment should be aware of?
7. Are there any clinical trials of CCTA underway whose results are likely to be viewed by physicians as setting the benchmark for understanding of its clinical or cost-effectiveness?
8. How should the assessment handle the two different ways of presenting diagnostic accuracy results: per-patient vs. per-segment?
9. How should the number of undetectable segments be considered in evaluations of positive predictive value (PPV) using CCTA?
10. Should all incidental findings be considered in our appraisal, or should we limit their scope in some way (e.g., pulmonary nodules)?
11. Should the economic model assume that patients with diagnosed CAD receive future surveillance with CCTA or another modality?
12. Are there any key considerations to the costs that should or should not be included for CCTA or ICA, such as:
 - a. Anesthesia costs for ICA
 - b. Further evaluation and management of incidental findings on CCTA