

**Washington State Health Care Authority, HTA Program
Coronary CT Angiography
Final Key Questions and Background**

Introduction and Request for Public Comment

HTA has selected Coronary CT Angiography to undergo a health technology assessment where an independent vendor will systematically review the evidence available on the safety, efficacy, and cost-effectiveness. Important clinical questions have not been answered about the safety and effectiveness of the diagnostic test and its use.

At this phase, HTA is requesting public comments on the key questions. Key questions will direct the gathering, review, and summary of the evidence for the report. The HTA considers all public comments and we are particularly interested in comments that include information on whether the key questions will identify available evidence about the technology's safety, efficacy, effectiveness, and cost effectiveness. Once the key questions are finalized, the vendor will search for evidence and compile a draft report. The draft report will then be published for review and public comment.

Proposed Key Questions

For patients with suspected coronary artery disease requiring evaluation of the coronary arteries:

1. What is the evidence that CCTA has the ability to diagnose or exclude coronary artery disease compared to current tests including conventional coronary angiography?
 - Describe sensitivity, specificity, and other key test characteristics of CCTA
2. What is the evidence that CCTA improves health outcomes for patients with suspected coronary artery disease (including reduced need for other tests, more accurate diagnosis)
3. What is the evidence about the appropriate patient selection criteria and follow up care?
4. What is the evidence of CCTA's safety profile?
5. What is the evidence about the cost impact of CCTA?

Issues that will be described in the background to set context for this review:

- Test characteristics of CCTA variance according to the type of scanning machine and software, patient preparation, reader training, and other operational factors

Technology Background

Disease: Heart disease is the leading cause of death in the United States and is a major cause of disability. Almost 700,000 people, 29% of US deaths, die of heart disease in the U.S. each year. Heart disease is a term that includes several more specific heart conditions. The most common heart disease in the United States is coronary artery disease (CAD), which can lead to heart attack. CAD is a narrowing of the coronary arteries that results in an insufficient supply of oxygen to the heart muscle and is a leading cause of death in the US and developed countries. CAD can affect one or more arteries and be either total or partial narrowing. CAD may be asymptomatic or lead to chest pain (angina), heart attack- myocardial infarction (MI), or death.

Technology: Coronary computed tomography angiography (CCTA) involves the use of CT scans and an injected dye to develop computer-aided, 3-dimensional images of the artery. Multi-slice CT scanners first received FDA approval in 1998, and their use (as well as level of precision) has evolved rapidly since then.

CT angiography in general has proliferated into multiple indications, including head and neck vascular imaging (e.g., for occlusive carotid arterial disease), diagnosis of aortic dissection or thoracic aortic aneurysm, detection of pulmonary embolism, diagnosis of peripheral arterial disease, visualization of the abdominal vascular system (e.g., for abdominal aortic aneurysm), and detection of a variety of cardiac and cerebrovascular congenital abnormalities. The focus of this review, however, is on the use of CT angiography for detection of coronary heart disease, given the condition's high prevalence (it is the most common cause of cardiac disease) and importance (it is the leading cause of death in the U.S. for both men and women).

CCTA has been suggested as an alternative to conventional coronary angiography (CA), which involves placement of a catheter and injection of contrast material into a large artery or vein, followed by 2-dimensional visualization using standard X-rays. The potential advantages of CCTA over conventional angiography include multiple-angle and multiple-plane visualization, improved visualization of soft tissues and adjacent anatomy, and a lower degree of invasiveness. Potential disadvantages of CCTA include increased radiation exposure, the possibility of incidental findings in adjacent anatomic structures, and the potential need for further testing.