

Centers for Medicaid Services CTA Announcement

CMS recently announced their proposal for coverage of Computed Tomographic Angiography (CTA) for the diagnosis of CAD for:

- symptomatic patients with chronic stable angina at intermediate risk of CAD; or
- symptomatic patients with unstable angina at a low risk of short-term death and intermediate risk of CAD.

CMS is providing an opportunity for members of the medical community interested in CTA to participate in the gathering of clinical data by conducting and submitting clinical studies to support current and potential expanded coverage indications for CT Angiography. The following document outlines what CMS is proposing the principal investigators of CTA clinical studies seeking Medicare payment should submit.

HYPERLINK

"<https://mail.triadisotopes.com/exchweb/bin/redirect.asp?URL=http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=206>" \t "_blank" <http://www.cms.hhs.gov/mcd/viewdraftdecisionmemo.asp?id=206>
Decision Summary

The Centers for Medicare and Medicaid Services (CMS) proposes the following be added to section 220.1 (Appendix A) of the National Coverage Determination Manual titled "Computed Tomography":

The evidence is inadequate to conclude that cardiac computed tomographic angiography (CTA) is reasonable and necessary under section 1862(a)(1)(A) for the diagnosis of coronary artery disease (CAD); however, the agency believes the evidence is promising for two clinical indications and that coverage with evidence development (CED) would be appropriate for these indications under section 1862(a)(1)(E), based on the specific standards outlined below.

Therefore, CMS proposes Medicare coverage of CTA for the diagnosis of CAD for:

- symptomatic patients with chronic stable angina at intermediate risk of CAD; or
- symptomatic patients with unstable angina at a low risk of short-term death and intermediate risk of CAD.

Risk of CAD is determined by the Framingham risk score (FRS). Patients with FRS >20% are considered high risk; FRS of 10%-20% are considered intermediate risk (Keevil, 2007; Wilson, 1998).

A clinical study seeking Medicare payment for CTA for the diagnosis of CAD for the above clinical indications provided to the beneficiary pursuant to CED must address one or more of the following questions:

Does cardiac CTA have the ability to diagnose or exclude coronary artery disease as well as invasive coronary angiography?

Does coronary CTA reduce the need for invasive coronary angiography?

Does coronary CTA improve health outcomes for patients with acute chest pain who present in the emergency room or other setting?

CMS is requiring that the study meet the following standards:

The principal purpose of the research study is to test whether the intervention potentially improves the participants' health outcomes;

The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;

The research study does not unjustifiably duplicate existing studies;

The research study design is appropriate to answer the research question being asked in the trial;

The research study is sponsored by an organization or individual capable of executing the proposed trial successfully;

The research study is in compliance with Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is FDA-regulated, it also must be in compliance with 21 CFR Parts 50 and 56;

All aspects of the research study are conducted according to the appropriate standards of scientific integrity.

The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards;

The research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR §312.18(a) and the patient has no other viable treatment options;

The research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject;

The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than three years after the end of data collection.

The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on recruitment or retention of the underrepresented populations, the protocol must discuss why these criteria are necessary; and

The research study protocol explicitly discusses how the results are or are not expected to be generalizable

to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

The principal investigators of CTA clinical studies seeking Medicare payment should submit the following documentation to CMS and should expect to be notified when the CMS review is complete:

Complete study protocol;

Protocol summary;

Statement that the above study standards are met;

Statement that the study addresses at least one of the above questions related to CTA;

Complete contact information (phone number, email address and mailing address); and

Clinicaltrials.gov registration number.

The above information should be mailed to:

Steve E. Phurrough, MD, MPA

Director

Coverage and Analysis Group, CMS

Re: CTA

Mailstop C1-09-06

7500 Security Blvd.

Baltimore, MD 21244-1850

All other uses of cardiac CTA for the diagnosis of CAD are noncovered. Congress has not established a screening benefit for cardiac CTA for the diagnosis of CAD; thus the use of cardiac CTA to screen asymptomatic patients for CAD is also noncovered.

Cardiac CTA for uses other than the diagnosis of CAD remains at contractor discretion.

We are requesting public comments on this proposed determination pursuant to Section 731 of the Medicare Modernization Act. After considering the public comments, we will make a final determination and issue a final decision memorandum.