

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 85	Date: June 27, 2008
	Change Request 6098

SUBJECT: Cardiac Computed Tomographic Angiography (CTA)

I. SUMMARY OF CHANGES: Upon review of the available evidence, the Centers for Medicare and Medicaid Services has determined that the use of cardiac CTA to diagnosis coronary artery disease (CAD), shall remain at local contractor discretion, and no national coverage determination (NCD) is appropriate at this time.

This addition to section 220.1 of Pub.100-03 of the NCD Manual entitled Computed Tomography makes no changes to the NCD. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

NEW / REVISED MATERIAL

EFFECTIVE DATE: MARCH 12, 2008

IMPLEMENTATION DATE: July 28, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
R	1/220.1/Computed Tomography

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question

and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

**Unless otherwise specified, the effective date is the date of service.*

Attachment – Business Requirements

Pub. 100-03	Transmittal: 85	Date: June 27, 2008	Change Request: 6098
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SUBJECT: Cardiac Computed Tomographic Angiography

Effective Date: March 12, 2008

Implementation Date: July 28, 2008

I. GENERAL INFORMATION

A. Background: Cardiac computed tomographic angiography (CTA) is a noninvasive method, using intravenous contrast, to visualize the coronary arteries (or other vessels) using high resolution, high speed computed tomography (CT).

B. Policy: After examining the medical evidence, the Centers for Medicare and Medicaid Services (CMS) has determined that no national coverage determination (NCD) is appropriate at this time (March 12, 2008). Section 1862(a)(1)(A) of the Social Security Act decisions should be made by local contractors through a local coverage determination process or case-by-case adjudication.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
6098.1	Contractors shall be aware that section 220.1, Computed Tomography, of Pub. 100-03 of the NCD Manual, remains unchanged. Therefore, all claims for CTA used to diagnose coronary artery disease shall continue to be determined by local Medicare Contractor discretion.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
6098.2	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters"	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	<p>listserv.</p> <p>Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.</p>										

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below: N/A

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

B. For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

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Post-Implementation Contact(s): Appropriate RO

VI. FUNDING

A. No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

B. The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**Medicare National Coverage
Determinations Manual
Chapter 1, Part 4 (Sections 200 – 310.1)
Coverage Determinations**

Table of Contents
(Rev. 85, 06-27-08)

220.1 – *Computed* Tomography

220.1 – *Computed* Tomography

(Rev. 85, Issued: 06-27-08, Effective: 03-12-08, Implementation: 07-28-08)

A. General

Diagnostic examinations of the head (head scans) and of other parts of the body (body scans) performed by computerized tomography (CT) scanners are covered if medical and scientific literature and opinion support the effective use of a scan for the condition, and the scan is: (1) reasonable and necessary for the individual patient; and (2) performed on a model of CT equipment that meets the criteria in C below.

CT scans have become the primary diagnostic tool for many conditions and symptoms. CT scanning used as the primary diagnostic tool can be cost effective because it can eliminate the need for a series of other tests, is noninvasive and thus virtually eliminates complications, and does not require hospitalization.

B. Determining Whether a CT Scan Is Reasonable and Necessary

Sufficient information must be provided with claims to differentiate CT scans from other radiology services and to make coverage determinations. Carefully review claims to ensure that a scan is reasonable and necessary for the individual patient; i.e., the use must be found to be medically appropriate considering the patient's symptoms and preliminary diagnosis.

There is no general rule that requires other diagnostic tests to be tried before CT scanning is used. However, in an individual case the contractor's medical staff may determine that use of a CT scan as the initial diagnostic test was not reasonable and necessary because it was not supported by the patient's symptoms or complaints stated on the claim form; e.g., "periodic headaches."

Claims for CT scans are reviewed for evidence of abuse, which might include the absence of reasonable indications for the scans, an excessive number of scans, or unnecessarily expensive types of scans considering the facts in the particular cases.

C. Approved Models of CT Equipment

1. Criteria for Approval

In the absence of evidence to the contrary, the contractor may assume that a CT scan for which payment is requested has been performed on equipment that meets the following criteria:

- a. The model must be known to the Food and Drug Administration (*FDA*),
and
- b. Must be in the full market release phase of development.

Should it be necessary to confirm that those criteria are met, ask the manufacturer to submit the information in C.2. If manufacturers inquire about obtaining Medicare approval for their equipment, inform them of the foregoing criteria.

2. Evidence of Approval

- a. The letter sent by the Bureau of Radiological Health, FDA, to the manufacturer acknowledging the FDA's receipt of information on the specific CT scanner system model submitted as required under Public Law 90-602, "The Radiation Control for Health and Safety Act of 1968."
- b. A letter signed by the chief executive officer or other officer acting in a similar capacity for the manufacturer which:
 - i.. Furnishes the CT scanner system model number, all names that hospitals and physicians' offices may use to refer to the CT scanner system on claims, and the accession number assigned by FDA to the specific model;
 - ii. Specifies whether the scanner performs head scans only, body scans only (i.e., scans of parts of the body other than the head), or head and body scans;
 - iii. States that the company or corporation is satisfied with the results of the developmental stages that preceded the full market release phase of the equipment, that the equipment is in the full market release phase, and the date on which it was decided to put the product into the full market release phase.

D. Mobile CT Equipment

CT scans performed on mobile units are subject to the same Medicare coverage requirements applicable to scans performed on stationary units, as well as certain health and safety requirements recommended by *the* Health Resources and Services Administration. As with scans performed on stationary units, the scans must be determined medically necessary for the individual patient. The scans must be performed on types of CT scanning equipment that have been approved for use as stationary units (see C above), and must be in compliance with applicable State laws and regulations for control of radiation.

1. Hospital Setting

The hospital must assume responsibility for the quality of the scan furnished to inpatients and outpatients and must ensure that a radiologist or other qualified physician is in charge of the procedure. The radiologist or other physician (i.e., one who is with the mobile unit) who is responsible for the procedure must be approved by the hospital for similar privileges.

2. Ambulatory Setting

If mobile CT scan services are furnished at an ambulatory health care facility other than a hospital-based facility, e.g., a freestanding physician-directed clinic, the diagnostic procedure must be performed by, or under the direct personal supervision of, a radiologist or other qualified physician. In addition, the facility must maintain a record of the attending physician's order for a scan performed on a mobile unit.

3. Billing for Mobile CT Scans

Hospitals, hospital-associated radiologists, ambulatory health care facilities, and physician owner/operators of mobile units may bill for mobile scans as they would for scans performed on stationary equipment.

4. Claims Review

Evidence of compliance with applicable State laws and regulations for control of radiation should be requested from owners of mobile CT scan units upon receipt of the first claims. All mobile scan claims should be reviewed very carefully in accordance with instructions applicable to scans performed on fixed units, with particular emphasis on the medical necessity for scans performed in an ambulatory setting.

E. Multi-Planar Diagnostic Imaging (MPDI)

In usual CT scanning procedures, a series of transverse or axial images are reproduced. These transverse images are routinely translated into coronal and/or sagittal views. MPDI is a process which further translates the data produced by CT scanning by providing reconstructed oblique images which can contribute to diagnostic information. MPDI, also known as planar image reconstruction or reformatted imaging, is covered under Medicare when provided as a service to an entity performing a covered CT scan.

F. Computed Tomographic Angiography (CTA)

CTA is a general phrase used to describe a non-invasive method, using intravenous contrast, to visualize the coronary arteries (or other vessels) using high-resolution, high-speed CT.

After examining the medical evidence, the Centers for Medicare and Medicaid Services (CMS) has determined that no national coverage determination (NCD) is appropriate at this time (March 12, 2008). Section 1862(a)(1)(A) of the Social Security Act decisions should be made by local contractors through a local coverage determination process or case-by-case adjudication. See Heckler v. Ringer, 466 U.S. 602, 617 (1984) (Recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication.). See also, 68 Fed. Reg. 63692, 63693 (November 7, 2003)

(This NCD last reviewed March 2008.)