
CMS Manual System

Pub. 100-03 Medicare National Coverage Determinations

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 25

Date: OCTOBER 15, 2004

CHANGE REQUEST 3489

NOTE: This Transmittal replaces Transmittal 22, dated October 1, 2004, which you were instructed to hold until further notice. We have changed the effective and implementation dates to October 12, 2004, to reflect the official posting of the National Coverage Determination. All other information remains the same. You may disseminate this instruction to the public as usual.

SUBJECT: Percutaneous Transluminal Angioplasty (PTA)

I. SUMMARY OF CHANGES: Medicare will cover PTA of the carotid artery concurrent with placement of an FDA-approved carotid stent for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. The CMS determines that coverage of PTA of the carotid artery is considered reasonable and necessary under these circumstances.

Performance of PTA of the carotid artery concurrent with carotid stent placement when furnished outside of FDA-approved protocols governing both FDA-required post-approval studies and FDA Category B IDE clinical trials remains noncovered.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: October 12, 2004
IMPLEMENTATION DATE: October 12, 2004

(This revision to §20.7 of Pub. 100-03 is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on a Medicare Advantage Organizations. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. 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: **(R = REVISED, N = NEW, D = DELETED)**

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	1/20.7 Percutaneous Transluminal Angioplasty (PTA) (Effective October 12, 2004)

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

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

Medicare National Coverage Determinations Manual

Chapter 1 - Coverage Determinations

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(Rev.25, 10-15-04)

20.7 - Percutaneous Transluminal Angioplasty (PTA)

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(Rev. 25, Issued 10-15-04, Effective: 10-12-04, Implementation: 10-12-04)

A. General

This procedure involves inserting a balloon catheter into a narrow or occluded blood vessel to recanalize and dilate the vessel by inflating the balloon. *The objective of PTA is to improve the blood flow through the diseased segment of a vessel so that vessel patency is increased and embolization is decreased. With the development and use of balloon angioplasty for treatment of atherosclerotic and other vascular stenoses, PTA (with and without the placement of a stent) is a widely used technique for dilating lesions of peripheral, renal, and coronary arteries.*

B. Nationally Covered Indications

The PTA is covered to treat the following indications:

1. Atherosclerotic obstructive lesions:

- In the lower extremities, i.e., the iliac, femoral, and popliteal arteries, or in the upper extremities, i.e., the innominate, subclavian, axillary, and brachial arteries. The upper extremities do not include head or neck vessels.
- Of a single coronary artery for patients for whom the likely alternative treatment is coronary bypass surgery and who exhibit the following characteristics:
 - Angina refractory to optimal medical management;
 - Objective evidence of myocardial ischemia; and
 - Lesions amenable to angioplasty.
- Of the renal arteries for patients in whom there is an inadequate response to a thorough medical management of symptoms and for whom surgery is the likely alternative. The PTA for this group of patients is an alternative to surgery, not simply an addition to medical management.
- Of arteriovenous dialysis fistulas and grafts when performed through either a venous or arterial approach.

2. Effective July 1, 2001, Medicare covers PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the Food and Drug Administration (FDA)-approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials. The PTA of the carotid artery, when provided solely for the purpose of carotid artery dilation concurrent with carotid stent placement, is

considered to be a reasonable and necessary service only when provided in the context of such a clinical trial

3. *Effective October 12, 2004, Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. CMS determines that coverage of PTA of the carotid artery is reasonable and necessary under these circumstances.*

C. *Nationally Noncovered Indications*

1. *Performance of PTA in the carotid artery when used to treat obstructive lesions outside of FDA-approved protocols governing Category B IDE clinical trials and outside of FDA-required post approval studies remains a noncovered service.*

2. *Performance of PTA to treat obstructive lesions of the vertebral and cerebral arteries remains noncovered. The safety and efficacy of these procedures are not established.*

D. *Other*

All other indications for PTA for which CMS has not specifically indicated coverage remain noncovered.

(This NCD last reviewed September 2004.)