

# Carotid Artery Disease Coverage Policy in the United States

A history of CMS decisions for angioplasty and carotid artery stenting coverage.

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Medicare began reviewing carotid artery atherosclerosis treatment more than 32 years ago.<sup>1</sup> The purpose of this article is to provide the history of coverage policy development by the HealthCare Financing Administration (HCFA), subsequently named the Centers for Medicare & Medicaid Services (CMS), for the treatment of carotid artery atherosclerotic disease in Medicare beneficiaries.

The first published decision was a noncoverage policy in 1984 for percutaneous transluminal angioplasty (PTA) of the carotid arteries. An expansion of coverage followed on March 19, 2001, for carotid artery stenting (CAS). This National Coverage Determination (NCD) was issued to cover PTA concurrent with CAS in Category B IDE studies. In all subsequent reconsiderations, CMS has focused on the same factors in their analyses: (1) strengths and weaknesses of the studies, (2) generalizability of the study to the Medicare population, (3) relative magnitude of the intervention risks and benefits, (4) patient criteria, (5) benchmark mortality rates, and (6) questions of sufficient evidence for patient outcomes.

An overview of the current NCD process described in the next section provides the framework for CMS reconsideration reviews and decisions. The subsequent sections are summaries of CMS considerations for coverage of CAS in chronological order.

## NCD PROCESS OVERVIEW

On September 26, 2003, a notice was published in the Federal Register describing the current NCD process via one of three tracks.<sup>2</sup> Track No. 1 is a request by any

external party for a new coverage policy. Track No. 2 is generated by an aggrieved party for a new NCD for treatment that has a noncoverage policy or for a national coverage policy that does not exist. Track No. 3 is a request generated internally by CMS for a new policy or reconsideration of an existing NCD. Any track follows the same NCD process, which may take up to 270 days for the CMS website posting of the NCD Notice, the proposed decision, the final decision, and the NCD effective date with provider instructions. This process includes public comment periods, CMS review of the request, evidence assessment, and generation of a Health Technology Assessment (HTA) if requested.

Another evaluation mechanism for CMS is to convene a MEDCAC (Medicare Evidence Development & Coverage Advisory Committee) meeting to provide guidance and expert advice on a specific treatment of interest. Experts are invited to consider questions that CMS has presented and base their answers on the strength of the evidence. Table 1 illustrates the CMS expected time period for the NCD development or reconsideration process of each phase.

## 1981 to 2000: The Beginning

Before 1981, Medicare contractors had the discretion to determine coverage of PTA for noncoronary arteries because there was no HCFA national coverage policy. In 1984, a noncoverage policy was published for this procedure. There were several assessments, reviews, and discussions on expansion of PTA and stent implantation in the carotid arteries through 2000. A summary of these actions is listed in Table 2.

TABLE 1. NCD PROCESS OVERVIEW

NCD Process Phases	Time Periods	Action	Notice of Public Meeting
NCD Notice: CMS website publication of the request (by track No. 1, 2 or 3) for a new NCD or reconsideration of a current NCD	1 to 30 days	Public comment period	<b>MEDCAC Meeting</b> Note: CMS may convene a MEDCAC meeting during any phase or other times
	31 to 90 days	CMS review of public comments, evidence, request an HTA and development of proposed decision	
Proposed NCD Decision: Posted on the CMS website	91 to 120 days	Public comment period	
	121 to 179 days	CMS review of public comments and development of final decision	
Final NCD Decision: Posted on the CMS website	180 days	Publication of the CMS response to public comments and discussion of final decision	
Effective Date and Medicare Manual Instructions	181 to 270 days	CMS development and publication of the NCD with the effective date for inclusion in the Medicare manuals	

#### 2001: First Coverage: PTA Concurrent With Carotid Stenting in Category B FDA IDE Studies (CAG-00085N)

CMS generated a request to reconsider the expansion of the PTA NCD to cover payment of routine costs for Category B FDA IDE carotid stenting clinical trials. The results of several clinical studies conducted outside of the United States were reviewed. CMS was informed that the FDA had approved Category B IDE CAS clinical trials, which were beginning to enroll subjects. Based on this review and the new United States studies, CMS approved and implemented expanded coverage in 2001 for these FDA-approved Category B IDE studies.

#### 2004: Postapproval Studies Expansion (CAG-00259N)

An internal request by CMS was generated to expand coverage to include FDA postapproval CAS clinical trials. The FDA had approved one carotid stent, and because the NCD only covered Category B IDE clinical trials, coverage would no longer be available for this approved stent. CMS approved coverage expansion for postapproval studies in 2004, stating that coverage would be appropriate based on “the importance of carotid artery stenosis as a risk factor for stroke and the importance of making available new FDA-approved technologies to Medicare beneficiaries.”<sup>3</sup>

#### 2005: First Patient Criteria Expansion (CAG-00085R)

CMS received an external request to expand coverage for CAS to patients not in an FDA IDE Category B or

postapproval clinical trial for FDA-approved carotid stents. This request was based on published evidence of recent data from ongoing clinical studies. After review of the evidence and health technology assessments, CMS approved expansion to patients with symptomatic carotid artery atherosclerosis at high risk for carotid endarterectomy (CEA) with  $\geq 70\%$  stenosis. This coverage was limited to an FDA-approved carotid stent when implanted using an embolic protection device (EPD). Coverage for other patients remained limited to participation in FDA IDE or postapproval clinical trials.

CMS established another condition of coverage, as well. In order for a hospital to receive payment under the CAS NCD, it must meet the newly defined criteria and be approved through the CMS certification process as described in the CAS NCD. To be certified, a hospital must submit to CMS that it meets the NCD minimum standards, be an FDA-approved site for a CAS Category B IDE or postapproval study, and collect data on all CAS procedures.

#### 2006: Postapproval Extension Studies

CMS acknowledged that upon completion of a postapproval study, use of an FDA-approved stent would not be covered for patients other than those who were symptomatic high risk for CEA with  $\geq 70\%$  stenosis. To provide continued coverage for other Medicare beneficiaries, CMS established a new study category termed postapproval extension studies. In 2006, CMS published instructions (Transmittal 951 for

**TABLE 2. REVIEW OF PTA AND STENT EXPANSION FROM 1981 TO 2000**

Year	Action
1981	Office of Health Technology Assessment evaluated the effectiveness of PTA on noncoronary vessels and approved a national coverage policy for lower extremity vessels but not for carotid arteries.
1984 Noncoverage	HCFA issued a national noncoverage policy for carotid artery PTA after reviewing an Office of Health Technology Assessment assessment of published literature for CAS in the Coverage Issues Manual §50-32.
1993	Technology Advisory Committee reviewed literature plus information submitted by the Society of Cardiovascular and Interventional Radiology. No coverage expansion was approved for carotid artery PTA.
1997	Technology Advisory Committee reviewed published literature of carotid artery PTA concurrent with stenting. Since there were only a few small nonrandomized studies, it was concluded this treatment was still investigational and remained noncovered.
1998 to 2000	CMS received letters and participated in conference calls discussing coverage expansion for CAS clinical studies (CREST and SAPHIRE).

Change Request 5088) in the Pub. 100-04 Medicare Claims CMS Manual System, describing the extension study approval process.<sup>4</sup>

#### **2007: No Expansion Approval (CAG-00085R3)**

In mid-2006, CMS received an external request for coverage expansion in patient criteria. The proposed decision expanded coverage to high-risk CEA asymptomatic patients with  $\geq 80\%$  stenosis. It excluded octogenarians but provided coverage in Category B IDE or postapproval studies, as well as other clarifications. Based on insufficient study results, CMS reversed the proposed decision and did not approve expansion of patient criteria in the final decision. In the final decision, CMS stated their continued concerns on the lack of randomized controlled trials (RCTs) comparing CEA to CAS with a comparison to best medical therapy (BMT) for asymptomatic patients. CMS also stated that other types of studies did not provide sufficient evidence or clear results to meet the American Heart Association (AHA) benchmark of 6% stroke and 3% death (major adverse events) rates.

#### **2008: No Expansion Approval (CAG-00085R6)**

Another external request for coverage expansion of patient criteria was received by CMS and considered. CMS did not approve expansion in the proposed or final decisions, citing that there was a lack of RCTs and other studies that provided adequate evidence of outcomes to the generalized Medicare population to support expanded coverage. A commenter stated that CMS should mandate the use of registries by all facilities as a condition of certification. CMS stated the issue

would have to be addressed in future reconsideration decisions.

#### **2009: No Expansion Approval, Revision for EPDs (CAG-00085R7)**

CMS generated an internal request to reconsider the CAS NCD. The evidence review was focused on asymptomatic patients. The proposed decision did not expand coverage criteria but did revise language for inclusion of any 510(k)-cleared embolic protection. CMS finalized this decision in December of 2009. At this time, CMS revised Pub. 100-04 Medicare Claims CMS Manual System to allow for a process and coverage of 510(k)-cleared embolic protection extension studies. CMS continued to cite the lack of RCTs with comparisons of CEA to CAS to BMT. CMS acknowledged that other study types might provide sufficient evidence to expand coverage if the data are of adequate quality, relevant to the Medicare population, and demonstrate health benefits.

In this decision, CMS and other stakeholders showed support for a formal accreditation process with a registry and benchmark requirements. CMS noted that there is no neutral third-party or multidisciplinary organization to provide facility certification and oversight. A revision was included to provide more specific instructions for the current hospital certification and recertification every 2 years.

#### **2012: MEDCAC Meeting**

CMS convened a MEDCAC meeting on January 25, 2012, to review published literature and HTAs, as well as vote on specific questions related to carotid artery

TABLE 3. SUMMARY OF CMS CAS NCD DECISIONS

Reconsideration Requester	Reconsideration Opened	Request Summary	Final Decision	Final Decision Summary
Internal CAG-00085N	12/18/2000	Cover PTA with carotid stent procedures	03/19/2001	Cover PTA concurrent with carotid stent procedures in clinical trials that receive a Category B IDE designation from the FDA
External CAG-00085R	06/18/2004	Coverage for FDA-approved carotid artery stents with EPD for high-risk CEA symptomatic patients $\geq 70\%$ stenosis	03/17/2005	Finalized as proposed
		Coverage in Category B IDE and post-approval studies for CAS with EPD for high-risk CEA symptomatic patients with $\geq 50\%$ to $70\%$ stenosis and asymptomatic patients with $\geq 80\%$ stenosis		
		Hospital certification process		
Internal Revision Pub. 100-04 Medicare Claims Manual	Effective 02/28/2006	Instructions for postapproval extension studies for FDA approved carotid stents to provide continued coverage for Medicare beneficiaries other than symptomatic high-risk patients with $\geq 70\%$ stenosis.	06/12/2006	Instructions published for postapproval extension studies in the Medicare Claims Manual (Pub. 100-04)
External CAG-00085R3	08/02/2006	Expand coverage for carotid stenting outside of FDA Category B IDE clinical trials or postapproval studies	04/30/2007	No coverage expansion
External CAG-00085R6	02/01/2008	Expand carotid stenting patient criteria outside of FDA Category B IDE clinical trials or postapproval studies	10/14/2008	No coverage expansion
Internal CAG-00085R7	03/18/2009	Expand carotid stenting patient criteria outside of FDA Category B IDE clinical trials or postapproval studies	12/17/2009	No coverage expansion; revised language for EPD
Internal MED-CAC Meeting	N/A	Review literature and HTAs to answer CMS questions	01/25/2012	Questions answered by panel members were scored no higher than "Intermediate"

atherosclerotic treatment. Before the meeting, panel members were provided these documents for their review. Key opinion leaders were invited to present supplemental information, and panel members were able to ask questions for clarification. Other stakeholders were in attendance, as all MEDCAC meetings are open to the public.

CMS developed seven questions (with some sub-questions) for the panel to consider. CMS stated the following meeting objective: "The primary focus of this MEDCAC meeting is on whether or not CAS, CEA, and BMT improve outcomes in symptomatic and asymptomatic persons with carotid atherosclerosis." These questions required each panel member to indicate his or her confidence in the adequacy of evidence for vari-

ous carotid artery atherosclerotic treatments. The voting scale established was from 1 to 5, with 1 representing the lowest confidence and 5 representing the highest.

For questions that were addressed by the panel, none was scored higher than a 3 (intermediate). Scores varied depending on the patient population and treatment, as stated in the question. The meeting transcript and detailed questions may be found on the CMS website ([www.cms.gov](http://www.cms.gov)).

## SUMMARY

In the last 32 years of reviewing treatment for carotid artery stenosis, CMS published a noncoverage policy for PTA of the carotid arteries in 1984, expanded coverage

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for CAS concurrent with PTA in 2001, and approved another expansion for a limited set of patient criteria in 2005. Also in the 2005 decision, CMS approved coverage of Category B IDE postapproval studies; in 2006, CMS created a new type, defined as postapproval extension studies. In the last 7 years, CMS has not approved any further coverage expansion after reviewing three reconsiderations and convening a MEDCAC meeting. Table 3 provides a chronological summary of these actions. As a result, the current CMS NCD provides CAS treatment coverage within the following criteria:

- Symptomatic patients who are high risk for CEA with  $\geq 70\%$  stenosis and coverage.
- All other patients if they are enrolled in a Category B FDA IDE approval, postapproval, or extension study.

CMS has consistently stated similar conclusions in the last three reconsiderations of no approval for coverage expansion. This includes concerns with current evidence and discussion of study results necessary to expand coverage for CAS as listed:

- Sufficient evidence that CAS meets the American Heart Association MAE rates of 6% for stroke and 3% for death.
- RCTs comparing CEA, CAS, and BMT.
- Other types of studies may support coverage expansion if they provide data of adequate quality that are relevant to the Medicare population and demonstrate health benefits.
- CMS would be supportive of a formal accreditation process with registry and benchmark requirements if facility certification and oversight were provided by a neutral third-party or multidisciplinary organization. ■

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