Department of Health and Human Services OFFICE OF INSPECTOR GENERAL

PEER REVIEW ORGANIZATION (PRO) CRITIERIA FOR CAROTID ENDARTERECTOMY



AUGUST 1992 OEI-03-91-00150

EXECUTIVE SUMMARY

PURPOSE

This report (1) compares Peer Review Organizations' (PRO) preprocedure review criteria for carotid endarterectomy and (2) examines how these criteria affect denial rates. A companion report entitled "Preprocedure Review Costs for Carotid Endarterectomy" (OEI-03-91-00152) determined that preprocedure review for carotid endarterectomy was not cost effective. This additional analysis was conducted to determine if PRO criteria affected these outcomes and whether selected criteria would result in higher denial rates.

BACKGROUND

Surgeons perform carotid endarterectomy when the carotid arteries leading to the brain are blocked and blood flow becomes restricted. The procedure involves dissecting the neck below the ears, cutting the carotid arteries open lengthwise, and removing the accumulated plaque.

The Health Care Financing Administration (HCFA) required preprocedure review for all carotid endarterectomies covered by Medicare until October 1, 1991, when all required preprocedure reviews were eliminated. However, a PRO may request to continue preprocedure review if it can prove it is cost effective and would improve quality of care.

Under preprocedure review, each PRO developed review criteria and diagnostic indicators for approving carotid endarterectomy. Criteria are general standards on which PRO approval is based; diagnostic indicators are measurements or test results which substantiate the criteria.

There is no national consensus on when carotid endarterectomy is appropriate. Ongoing National Institutes of Health studies are addressing this issue.

METHODOLOGY

We analyzed all PROs' 1991 preprocedure review criteria for carotid endarterectomy. We compared criteria by State and identified the criteria which PROs used most frequently. We analyzed the number of PRO preprocedure requests and denials by State, and compared denial rates for carotid endarterectomy among the different criteria types.

FINDINGS

Two-thirds of PROs use three primary medical criteria to evaluate carotid endarterectomy: symptomatic stenosis, asymptomatic stenosis, and stroke history.

- Diagnostic indicators used to substantiate medical criteria vary from PRO to PRO.
- The relationship between PROs' criteria selection and denial rates is uncertain. Statistically, stroke history had an impact on denial rates. However, this impact should be viewed with caution since it is skewed by one State's high denial rate.
- PROs in eight States account for 79 percent of all denials. Yet, they share the same criteria and diagnostic indicators as PROs with no denials.
- Except for patients with severe symptomatic stenosis, the benefits of carotid endarterectomy are unclear.

CONCLUSION

Under preprocedure review, the PROs allowed carotid endarterectomy surgery for a wide range of diagnostic indicators. Differences among PROs may have resulted from the lack of objective medical data outlining when carotid endarterectomy was beneficial. It is difficult to develop criteria for preventing unnecessary surgery when there is no clear data on when surgery is necessary or beneficial.

When creating criteria for surgical procedures where there is little objective medical data, PROs have two choices. They can allow surgery for a greater range of diagnostic criteria where the benefits from the surgery have yet to be proven. Or they can deny surgery for all but a very select subset of criteria.

However, there is no perfect choice. Under the first option, there may be certain patients who have surgery that future research proves is unnecessary and ineffective. The second option may exclude patients from having surgery that is later found to be effective for their particular circumstances.

When reviewing the PROs' criteria in light of the new research on carotid endarterectomy, most PROs seem to have selected criteria that would fall under the first option. As of this time, research has proven carotid endarterectomy beneficial only for patients with severe stenosis (70 percent or more). For this particular criterion, the majority of PROs allowed surgery when there was stenosis of 50 percent or more.

The PROs' carotid endarterectomy criteria did not have a clear effect on denial rates. This conclusion provides further support for HCFA's decision to eliminate the preprocedure review requirement for carotid endarterectomies.

TABLE OF CONTENTS

EXECUTIVE SUMMARY	
INTRODUCTION	1
FINDINGS	
Medical Criteria	. 6
Diagnostic Indicators	. 6
Criteria and Denial Rates	. 8
States with Higher Denial Rates	12
Benefits of Surgery	12
CONCLUSION	13
APPENDIX A: Description of PRO Preprocedure Review Process	A- 1
APPENDIX B: PRO Preprocedure Requests and Denials	B-1
APPENDIX C: Matrix and Synopsis of State Criteria	C <u>-</u> 1

INTRODUCTION

PURPOSE

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BACKGROUND

Carotid Artery Occlusion: Causes, Risks, and Treatment

As shown in Illustration I, two internal carotid arteries provide the brain's primary blood supply. Individuals often experience atherosclerosis of these arteries as they age. Atherosclerosis is the accumulation of plaque or lesions inside the arterial walls.

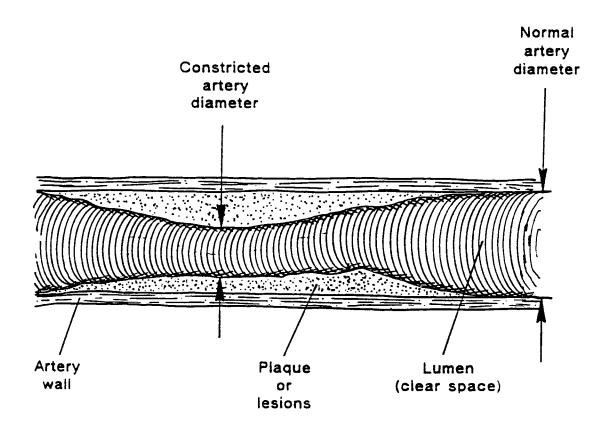
Right common artery
Right subclavian
artery
Brachiocephalic
trunk

Internal carotid artery
Carotid bifurcation
Left common carotid artery
Aortic arch

Illustration 1: Carotid Arteries

Atherosclerosis causes the carotid arteries to narrow in size; this narrowing restricts blood flow to the brain producing potential health risks (see Illustration II). Individuals usually can tolerate gradual occlusion or blockage of one carotid artery. However, serious occlusion of one or both arteries can cause massive strokes or transient ischemic attacks (TIA). Transient ischemic attacks are "mini-strokes" caused by a temporary decrease in the brain's blood supply.

Illustration II: Constricted Artery
Resulting from Atherosclerosis



Occlusion of the carotid arteries can be treated surgically or non-surgically. Carotid endarterectomy is the preferred surgical procedure. It involves dissecting the neck below the ears, cutting the carotid arteries open lengthwise, and removing the accumulated plaque. The procedure entails considerable risks and side effects. However, neurosurgeons and vascular surgeons claim high rates of success in restoring blood flow.

The most common non-surgical treatment is anti-platelet medication, usually aspirin. Clinical studies show an aspirin every day reduces the risk of stroke. Other drug treatments are now being evaluated.

In recent years, the frequency of carotid endarterectomy has not increased due to medical appropriateness questions surrounding the procedure. Concerns include the qualifications of physicians performing the surgery, surgical settings, post-surgical neurological deficits, and high mortality rates.

PRO Preprocedure Review Requirements

In each State, HCFA contracts with a Utilization and Quality Control Peer Review Organization, commonly known as a PRO, to review the appropriateness and quality of surgery performed on Medicare beneficiaries.

Prior to October 1991, HCFA required PRO preprocedure review for all carotid endarterectomies covered by Medicare. On October 1, 1991, HCFA eliminated all required preprocedure review.¹ However, a PRO may request to continue preprocedure review if it can prove it is cost effective and would improve quality of care. At this time, HCFA has not given approval for any PRO to perform preprocedure review for carotid endarterectomy.

Preprocedure Review Criteria and Diagnostic Indicators

Under preprocedure review, each PRO developed review criteria and diagnostic indicators for approving carotid endarterectomy. Criteria are general standards on which PRO approval is based; diagnostic indicators are measurements or test results which substantiate the criteria.

Typically, PROs had committees which developed criteria and diagnostic indicators in consultation with State medical associations and a variety of individuals. In large States, specialty societies, such as vascular surgeons or neurosurgeons, were involved. In smaller States, the committees solicited individual physician opinions.

The PROs submitted the criteria and indicators to the HCFA regional office, which reviewed and approved them before they could be implemented. Once HCFA approved the criteria, the PROs were required to share them with providers.

A description of the PRO preprocedure review process is in Appendix A.

¹ HCFA, Directed Change Order (DCC 91-13): Cessation of Preadmission/ Preprocedure Review. The HCFA does allow preprocedure review for approved objectives, interventions under the quality intervention plan, and assistants at cataract surgery.

Relevant Studies

The National Institutes of Health (NIH) is supporting two large, multi-institutional, randomized trials. Both the Asymptomatic Carotid Atherosclerosis Study (ACAS) and the North American Symptomatic Carotid Endarterectomy Trial (NASCET) Collaborators examine the effectiveness of carotid endarterectomy in reducing arterial occlusion and preventing strokes.² Effectiveness of carotid endarterectomy is also being examined in the European Carotid Surgery Trial.³

In February 1991, the NIH issued a Clinical Alert detailing the benefits of carotid endarterectomy for certain individuals. The Agency for Health Care Policy and Research within the Department of Health and Human Services has also issued a report reviewing recent medical literature concerning carotid endarterectomy.⁴

METHODOLOGY

Data Collection

We obtained the PROs' prospective review criteria from HCFA. We confirmed and updated the criteria with 47 PRO officials representing all 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands during March 1991. In this report, we refer to these 53 jurisdictions as States.

From the PROs we requested numerical data and a description of their review procedures. The data requested for carotid endarterectomies included the number of preprocedure requests and denials.⁵ We asked States to provide us with calendar year 1990 data. However, some States supplied data from the Third Scope of Work for contract year 1990. This information is presented in Appendix B.

²North American Symptomatic Carotid Endarterectomy Trial Collaborators, "Beneficial Effect of Carotid Endarterectomy in Symptomatic Patients with High-Grade Carotid Stenosis," New England Journal of Medicine 1991;325:445-453.

³"MRC European Carotid Surgery Trial: Interim Results for Symptomatic Patients with Severe (70-99 percent) or with Mild (0-29 percent) Carotid Stenosis (UK Medical Research Council)," <u>Lancet</u>, June 25, 1991; 337(8752):1235-1243.

⁴U.S. Department of Health and Human Services, Public Health Service, Agency for Health Care Policy and Research, Office of Health Technology Assessment, <u>Carotid Endarterectomy (revised)</u>, AHCPR Health Technology Assessment Reports, July 1991, Number 5R.

⁵ The PROs report that final denial data could change as some denials were subject to reconsideration appeals.

Data Analysis

We analyzed all PRO criteria for carotid endarterectomy. We then identified the criteria which PROs used most frequently. Based upon advice from our health care consultant, we narrowed this selection to three primary medical criteria. We classified information within the three criteria based on similar medical definitions. The PROs do not always use similar terms to describe medical criteria. Therefore, we sometimes use one particular term which is representative of the PROs' various terminologies.

We categorized each PRO by the types of primary criteria it used. The PROs fell into four categories depending on the combination of the three criteria they used. To determine if PRO criteria affected denials, we calculated the number of denials for each of the four categories. We then compared denial numbers and rates among the four groups. To test for differences between the groups, we used a linear logistic analysis of categorical data. Each category of criteria was entered into the model and the significance of the estimated coefficients determined using Wald chi square statistics.⁶

Consultant services were secured under contract from the Villanova University College of Nursing.

⁶D.W. Hosmer and S. Lemeshow, <u>Applied Logistic Regression</u> (New York: John Wiley and Sons, Inc., 1989).

FINDINGS

TWO-THIRDS OF PROS USE THREE PRIMARY MEDICAL CRITERIA TO EVALUATE CAROTID ENDARTERECTOMY.

Sixty-six percent of the States (35 of 53) had PRO criteria which contained all three primary medical criteria. The remaining 18 States did not have all three criteria but various combinations of the medical criteria. The criteria were symptomatic stenosis, asymptomatic stenosis, and stroke history. Several States also use criteria other than the three primary criteria.

Symptomatic stenosis is a constriction of the carotid artery that results in physical symptoms such as TIAs. Asymptomatic stenosis is a constriction of the carotid artery resulting in no outward symptoms. A patient's previous stroke experiences comprise the stroke history criterion. A matrix and synopsis of individual State criteria is presented in Appendix C.

DIAGNOSTIC INDICATORS USED TO SUBSTANTIATE MEDICAL CRITERIA VARY FROM PRO TO PRO.

Even when States had the same medical criteria, the diagnostic indicators they required to substantiate the criteria differed.

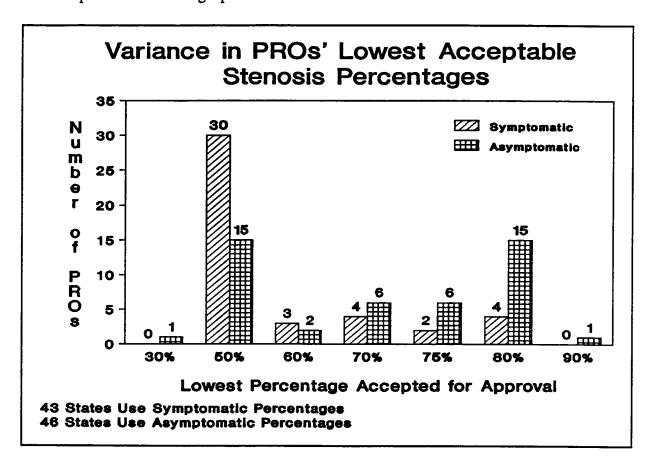
Symptomatic Stenosis

Every State used symptomatic stenosis as a criterion for approving carotid endarterectomy. The PROs' criteria generally included (1) patient symptoms and (2) demonstrated stenosis. Acceptable symptoms always included TIAs. Thirty-six States specifically mentioned this term. The other 17 States used more general definitions such as indicating a patient must demonstrate cerebrovascular insufficiency symptoms. A common manifestation of such insufficient circulation is a TIA. Some States also accepted other neurological conditions as symptoms warranting consideration of carotid endarterectomy.

States differed in their diagnostic indicators for symptomatic stenosis. Forty-three States used percentages which measured the amount of obstruction in the carotid artery as diagnostic indicators. Ten States did not specify stenosis percentages. These 10 States generally required diagnostic test findings that confirmed an atherosclerotic lesion.

For the 43 States using percentages, the percentage of stenosis required for surgery ranged from 50 to 95 percent. These States used 60 percentage indicators for symptomatic stenosis. Several States used more than one percentage indicator based

on the severity of specific physical symptoms. The lowest percentage accepted by each State is presented in the graph below.



Asymptomatic Stenosis

Diagnostic indicators for asymptomatic stenosis varied widely. Forty-six States addressed asymptomatic stenosis as a criterion. However, there was little commonality among the diagnostic indicators.

The 46 States had a total of 109 diagnostic indicators for asymptomatic stenosis. We found PROs representing 33 States used multiple indicators for this term. For example, in Minnesota, approval for asymptomatic carotid endarterectomy required:

80% stenosis, or greater than 70% stenosis with ulcerated plaque, indicated by arteriogram or digital subtraction angiography (DSA), or less severe stenosis demonstrated by arteriogram or DSA with one of the following: evidence of "silent-infarcts" on brain-affected side indicated by CT or MRI or cholesterol emboli to the eye.

Of the 109 diagnostic indicators for asymptomatic stenosis, 83 included stenosis percentages representing the amount of carotid artery narrowing. The lowest percentage accepted by each State is presented in the graph on the previous page. Some States used more than one percentage indicator, depending on other medical evidence. The 83 stenosis percentages varied from 30 to 90 percent. Most definitions (65 of 83) required 70 to 90 percent stenosis, unless an ulcerative lesion was present.

Stroke History

Diagnostic indicators for previous stroke were often loosely defined or not addressed. Thirty-nine States addressed stroke history. Their diagnostic indicators for previous stroke fell into five general categories.

- Sixteen States required a stroke patient to have significant improvement but did not define duration of the stroke.
- Eleven States required a patient's stroke to last over one week with significant improvement or recovery of neurological function.
- Six States accepted strokes without further qualifications.
- Five States defined strokes with multiple qualifiers (e.g., stroke in evolution and acute stoke).
- One State required strokes to have occurred within a certain period of time before the review.

THE RELATIONSHIP BETWEEN PROS' CRITERIA SELECTION AND DENIAL RATES IS UNCERTAIN.

Based on the types of primary criteria used, the PROs fell into four categories. The categories were: all three primary criteria (symptomatic stenosis, asymptomatic stenosis, and stroke history); symptomatic stenosis and asymptomatic stenosis; symptomatic stenosis and stroke history; and only symptomatic stenosis. The PROs denied 90 carotid endarterectomies out of 53,528 preprocedure requests in 1990, resulting in a national denial rate of 0.17 percent. Each of the four categories had a different denial rate but all were under 1 percent, as shown in the table on the next page.

The two PRO categories without stroke history had denial rates of 0.44 and 0.53 percent. Statistically, the two categories have significantly higher denial rates than those which included stroke history. Therefore, the decision to include or not include stroke history as a criteria seemed to impact a PRO's denial rates. However, the denials for one of the categories without stroke history came from only one State (AZ). This skewing of the data indicates that the effect of including stroke history in PRO criteria should be interpreted with caution.

Denial Rates for the Four Criteria Categories

Symptometic Stenosis	Asymptomatic Stenosis	Stroke History	Number of Requests	Number of Denials	Percent Denied
×	х	x	41,633	47	0.11
х	х		7005	31	0.44
X		X	3367	4	0.12
X			1523	8	0.53
	Total		53,528	90	0.17

The remaining two categories had denial rates relatively close to the national average. States with all three criteria had an average denial rate of 0.11 percent and States with symptomatic stenosis and asymptomatic stenosis criteria had a denial rate of 0.12 percent.

States with Symptomatic Stenosis, Asymptomatic Stenosis, and Stroke History Criteria

The 35 States using all 3 primary PRO criteria denied 47 of 41,633 requests. However, the majority of denials (34) were reported in just 6 States. Nearly half the States (17 of 35) did not report any denials at all.

As shown in the following table, these 35 States had a collective denial rate of 0.11 percent (47 of 41,633) compared to the national average of 0.17 percent. The 47 denials represented 52.2 percent (47 of 90) of all denials.

Denial Rates for States with Symptomatic Stenosis, Asymptomatic Stenosis, and Stroke History Criteria

State	No. of Requests	No. of Denials	Percent Denied
Alabama	1074	Not Available	Not Available
Alaska	26	00	0.00
Arkansas	801	0	0.00
California	5043	6	0.12
Colorado	284	4	1.41
D.C.	98	0	0.00
Florida	3869	0	0.00
Georgia	2941	11	0.03
Idaho	133	0	0.00
Kansas	1325	0	0.00
Maine	231	0	0.00
Maryland	870	1	0.11

State	No. of Requests	No. of Denials	Percent Denied
Massachusetts	762	1	0.13
Michigan	2598	7	0.27
Minnesota	364	0	0.00
Mississippi	658	0	0.00
Montana	161	0	0.00
New Jersey	1390	0	0.00
New York	1604	1	0.06
North Carolina	1304	1	0.08
North Dakota	127	0	0.00
Ohio	2922	5	0.17
Oklahoma	552	0	0.00
Oregon	786	1	0.13
Pennsylvania	2651	0	0.00
Puerto Rico	26	0	0.00
South Carolina	460	1	0.22
South Dakota	164	1	0.61
Tennessee	1653	8	0.48
Texas	3639	2	0.05
Vermont	55	2	3.64
Virginia	943	4	0.42
Washington	1138	1	0.09
Wisconsin	935	0	0.00
Wyoming	46	0	0.00
Total = 35 States	41,633	47	0.11

States with Symptomatic Stenosis and Asymptomatic Stenosis Criteria

Eleven States had criteria that addressed symptomatic stenosis and asymptomatic stenosis. This group denied 31 of 7,005 requests. However, the denial rate in the 11 States was affected by just 1 State, Arizona, which reported all 31 denials. At 5.72 percent, Arizona had the highest denial rate of all States. As shown below, Arizona's denial rate was more than 30 times the national average of 0.17 percent.

Denial Rates for States with Symptomatic and Asymptomatic Stenosis Criteria

State	No. of Requests	No. of Denials	Percent Denied
Arizona	542	31	5.72
Connecticut	444	0	0.00
Delaware	130	0	0.00

State	No, of Requests	No. of Denials	Percent Denied
Hawaii	102	0	0.00
Illinois	2230	0	0.00
Indiana	1504	0	0.00
Kentucky	963	0	0.00
Nevada	289	0	0.00
New Mexico	127	0	0.00
Virgin Islands	0	0	0.00
West Virginia	674	0	0.00
Total = 11	7005	31	0.44

States with Symptomatic Stenosis and Stroke History Criteria

Four States with criteria addressing symptomatic stenosis and stroke history denied 4 of 3,367 requests. The 4 denials represented 4.4 percent of all denials (4 of 90). Collectively, these States' denial rate of 0.12 percent (6 of 3,422) was comparable to the national average of 0.17 percent.

Denial Rates for States with Symptomatic Stenosis and Stroke History Criteria

State	No. of Requests	No. of Denials	Percent Denied
Louisiana	1356	1	0.07
Missouri	1660	2	0.12
New Hampshire	137	0	0.00
Utah	214	1	0.47
Total = 4 States	3367	4	0.12

States with Symptomatic Stenosis Criterion Only

The three States with criterion addressing only symptomatic stenosis denied eight requests or 8.9 percent of all denials. While these three States had a collective denial rate of 0.53 percent (8 of 1,523), six of the eight reported denials occurred in one State (Iowa).

Denial Rates for States with Symptomatic Stenosis Criterion Only

State	No. of Requests	No. of Denials	Percent Denied
Iowa	726	6	0.83
Nebraska	667	2	0.30
Rhode Island	130	0	0.00
Total = 3 States	1523	8	0.53

PROS IN EIGHT STATES ACCOUNT FOR 79 PERCENT OF ALL DENIALS. YET, THEY SHARE THE SAME CRITERIA AND DIAGNOSTIC INDICATORS AS PROS WITH NO DENIALS.

The PROs in eight States reported more than three-quarters of all carotid endarterectomy denials in 1990 (71 of 90). The cause of the higher denial rates in these eight States was not due to any particular combination of criteria or diagnostic indicators. In fact, other States with exactly the same criteria and diagnostic indicators as some of these eight States had much lower denial rates.

These eight States had various carotid endarterectomy criteria and diagnostic indicators. In six States (CA, CO, MI, OH, TN, and VA), PROs addressed all three national medical criteria. The Arizona PRO criteria addressed symptomatic and asymptomatic stenosis. The Iowa PRO criteria addressed only symptomatic stenosis.

Each of the eight States had four or more denials for carotid endarterectomy during 1990. The 71 denials (out of 14,711 requests) resulted in a denial rate of 0.48 percent, almost 3 times the national average of 0.17 percent. These States, however, accounted for only 27.5 percent of all preprocedure requests.

EXCEPT FOR PATIENTS WITH SEVERE SYMPTOMATIC STENOSIS, THE BENEFITS OF CAROTID ENDARTERECTOMY ARE UNCLEAR.

Two recent studies have concluded that carotid endarterectomy is beneficial for symptomatic patients with severe or high-grade stenosis (70 percent or more) of the internal carotid artery. However, no significant body of medical information shows that carotid endarterectomy is effective for lower-grade symptomatic stenosis or for asymptomatic stenosis.

Severe symptomatic stenosis is the one criterion where medical consensus exists. The North American Symptomatic Carotid Endarterectomy Trial Collaborators concluded that carotid endarterectomy is highly beneficial for patients with TIAs or non-disabling strokes who have high-grade stenosis. The European Carotid Surgery Trial also found that carotid endarterectomy was useful in treating stoke patients with severe carotid stenosis.

The benefits of carotid endarterectomy are not as clear for mild (0-29 percent) to moderate (30-69 percent) symptomatic stenosis or for asymptomatic stenosis. However, the European trial found that for mild stenosis the results indicated that the risks of surgery outweigh the benefits.

Among the 43 PROs who specified symptomatic stenosis percentages, 2 States' lowest acceptable percentage for surgery was 75 percent and for another 4 States it was 80 percent. However, the majority of States allowed carotid endarterectomy for 50 percent or greater symptomatic stenosis.

CONCLUSION

Under preprocedure review, the PROs allowed carotid endarterectomy surgery for a wide range of diagnostic indicators. Differences among PROs may have resulted from the lack of objective medical data outlining when carotid endarterectomy was beneficial. It is difficult to develop criteria for preventing unnecessary surgery when there is no clear data on when surgery is necessary or beneficial.

When creating criteria for surgical procedures where there is little objective medical data, PROs have two choices. They can allow surgery for a greater range of diagnostic criteria where the benefits from the surgery have yet to be proven. Or they can deny surgery for all but a very select subset of criteria.

However, there is no perfect choice. Under the first option, there may be certain patients who have surgery that future research proves is unnecessary and ineffective. The second option may exclude patients from having surgery that is later found to be effective for their particular circumstances.

When reviewing the PROs' criteria in light of the new research on carotid endarterectomy, most PROs seem to have selected criteria that fall under the first option. As of this time, research has proven carotid endarterectomy beneficial only for patients with severe stenosis (70 percent or more). For this particular criterion, the majority of PROs allowed surgery when there was stenosis of 50 percent or more.

The PROs' carotid endarterectomy criteria did not have a clear effect on denial rates. This conclusion provides further support for HCFA's decision to eliminate the preprocedure review requirement for carotid endarterectomies.

APPENDIX A

DESCRIPTION OF PRO PREPROCEDURE REVIEW PROCESS

The review process does not vary significantly among PROs. Physicians usually initiate the review process prior to performing a carotid endarterectomy. However, the life-threatening nature of a stroke sometimes requires retrospective approval.

Request for Review

Typically, the recommending surgeon, a staff member, or hospital staff telephones the PRO to review the patient's condition and seek preprocedure approval. Most PROs also accept mail requests and a few accept them via facsimile machine.

Initial Review by Registered Nurses

Registered nurses (RNs) review the initial preprocedure request, comparing the physician's diagnosis and the patient's symptoms against the PRO criteria for carotid endarterectomy. The RNs can approve the request based on the information the physician (or physician's representative) provides. If the request does not meet the criteria, the RN refers the case to the PRO physician advisor for review.

PRO Physician Review

The PRO physician conducts a second review of the requests which have not met the criteria, often contacting the recommending surgeon to discuss the case further. After the review, the PRO physician approves or denies the procedure.

When a PRO approves a preprocedure request, it assigns the case an approval number. When the PRO denies a request altogether, it typically informs both the surgeon and the patient of the decision, the rationale, and an explanation of appeal rights.

APPENDIX B

1990 PRO PREPROCEDURE REQUESTS AND DENIALS FOR CAROTID ENDARTERECTOMY BY STATE

STATE	NUMBER OF	NUMBER OF	PERCENT
PRO	REQUESTS	DENIALS	DENIED
ALABAMA	1,074	N/A*	N/A
ALASKA	26	0	0.00
ARIZONA	542	31	5.72
ARKANSAS	801	0	0.00
CALIFORNIA	5,043	6	0.12
COLORADO	284	4	1.41
CONNECTICUT	444	0	0.00
DELAWARE	130	0	0.00
D.C.	98	0	0.00
FLORIDA	3,869	0	0.00
GEORGIA	2,941	1	0.03
HAWAII	102	0	0.00
IDAHO	133	0	0.00
ILLINOIS	2,230	0	0.00
INDIANA	1,504	0	0.00
IOWA	726	6	0.83
KANSAS	1,325	0	0.00
KENTUCKY	963	0	0.00
LOUISIANA	1,356	1	0.07
MAINE	231	0	0.00
MARYLAND	870	1	0.11
MASSACHUSETTS	762	1	0.13
MICHIGAN	2,598	7	0.27
MINNESOTA	364	0	0.00
MISSISSIPPI	658	0	0.00
MISSOURI	1,660	2	0.12
MONTANA	161	0	0.00
NEBRASKA	667	2	0.30
NEVADA	289	0	0.00
NEW HAMPSHIRE	137	0	0.00
NEW JERSEY	1,390	0	0.00
NEW MEXICO	127	0	0.00
NEW YORK	1,604	1	0.06
NORTH CAROLINA	1,304	1	0.08
NORTH DAKOTA	127	0	0.00
OHIO	2,922	5	0.17
OKLAHOMA	552	0	0.00

STATE PRO	NUMBER OF REQUESTS	NUMBER OF DENIALS	PERCENT DENIED
OREGON	786	1	0.13
PENNSYLVANIA	2,651	0	0.00
PUERTO RICO	26	0	0.00
RHODE ISLAND	130	0	0.00
SOUTH CAROLINA	460	1	0.22
SOUTH DAKOTA	164	1	0.61
TENNESSEE	1,653	8	0.48
TEXAS	3,639	2	0.05
UTAH	214	1	0.47
VERMONT	55	2	3.64
VIRGINIA	943	4	0.42
VIRGIN ISLANDS	0	0	0.00
WASHINGTON	1,138	1	0.09
WEST VIRGINIA	674	0	0.00
WISCONSIN	935	0	0.00
WYOMING	46	0	0.00
NATIONAL TOTAL	53,528	90	0.17

All data is directly from PRO interviews conducted during this inspection. Some PROs were able to provide data for calendar year 1990 as requested; others chose to provide data for the Third Scope of Work contract year 1990.

^{*} We use the designation n/a to indicate that data was not available at the time of our interview.

APPENDIX C

MATRIX OF STATE CRITERIA FOR CAROTID ENDARTERECTOMY

STATE	SYMPTOMATIC	ASYMPTOMATIC	STROKE
ALABAMA*	X	X	X
ALASKA*	X	X	X
ARIZONA	X	X	
ARKANSAS*	X	X	X
CALIFORNIA*	X	X	X
COLORADO*	X	X	X
CONNECTICUT	X	X	
DELAWARE	X	X	
D.C.*	X	X	X
FLORIDA*	X	X	X
GEORGIA*	X	X	X
HAWAII	X	X	
IDAHO*	X	X	X
ILLINOIS	X	X	
INDIANA	X	X	
IOWA	X	<u> </u>	
KANSAS*	X	X	X
KENTUCKY	X	X	
LOUISIANA	X		X
MAINE*	X	X	X
MARYLAND*	X	X	X
MASSACHUSETTS*	X	X	X
MICHIGAN*	X	X	X
MINNESOTA*	X	X	X
MISSISSIPPI*	X	X	X
MISSOURI	X		X
MONTANA*	X	X	X
NEBRASKA	X		
NEVADA	X	X	
NEW HAMPSHIRE	X		X
NEW JERSEY*	X	X	X
NEW MEXICO	X	X	
NEW YORK*	X	X	X
NORTH CAROLINA*	X	X	X
NORTH DAKOTA*	X	X	X
ОНІО*	X	X	X
OKLAHOMA*	X	X	X
OREGON*	X	X	X
PENNSYLVANIA*	X	X	<u> </u>
PUERTO RICO*	X	X	X

STATE	SYMPTOMATIC	ASYMPTOMATIC	STROKE
RHODE ISLAND	X		
SOUTH CAROLINA*	X	X	X
SOUTH DAKOTA*	X	X	X
TENNESSEE*	X	X	X
TEXAS*	X	X	X
UTAH	X		X
VERMONT*	X	X	X
VIRGINIA*	X	X	X
VIRGIN ISLANDS	X	X	
WASHINGTON*	X	X	X
WEST VIRGINIA	X	X	
WISCONSIN*	X	X	X
WYOMING*	X	X	X
TOTALS	53	46	39

^{*} INCLUDES ALL THREE CRITERIA

SYNOPSIS OF STATE CRITERIA FOR CAROTID ENDARTERECTOMY

Alabama

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have lateralized transient neurological dysfunction involving speech, reason, motor, or sensory function, stroke, or drop attacks (vertebral-basilar ischemia). And:

Imaging: Angiography must demonstrate stenosis $\geq 70\%$, stenosis $\geq 60\%$ with ulceration, deep ulceration related to TIAs, or complete unilateral occlusion with stenosis $\geq 50\%$ on the other side.

ASYMPTOMATIC STENOSIS: The patient must have (1) a bruit, ultrasonic stenosis $\geq 70\%$, and angiographic stenosis $\geq 70\%$; or (2) complete unilateral occlusion with stenosis $\geq 50\%$ on the other side.

STROKE: Stroke is defined as a recent stroke with good to excellent recovery of function.

OTHER: Carotid-subclavian shunt warrants carotid endarterectomy.

Alaska, Idaho, & Washington

SYMPTOMATIC STENOSIS:

Symptoms: Patient must have at least one TIA, amaurosis fugax, stroke, or cholesterol emboli in the retinal artery. And:

Imaging: Imaging must be positive for either an ulcerated plaque or $\geq 50\%$ stenosis on the affected side.

ASYMPTOMATIC STENOSIS: Noninvasive study, arteriograph, or digital subtraction angiography must demonstrated ≥ 80% stenosis or an ulcerated plaque.

STROKE: Stroke (CVA) is not defined.

Arizona, Hawaii, & Nevada

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have amaurosis fugax, tingling limbs of face (paresthesia), paresis (or paralysis), dizziness, diplopia (double vision), or vertigo. And:

Imaging: Angiography must demonstrate $\geq 50\%$ unilateral stenosis of the common or internal carotid, $\geq 50\%$ bilateral stenosis, internal carotid occlusion associated with $\geq 50\%$ contralateral stenosis, or an ulcerated plaque.

ASYMPTOMATIC STENOSIS: Angiography must demonstrate $\geq 70\%$ unilateral internal or common carotid stenosis, $\geq 50\%$ stenosis in the presence of a contralateral internal or common carotid, or a total occlusion.

STROKE: Not addressed.

OTHER: None.

Arkansas

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have classical TIAs with hemiparesis, hemianesthesia, or dysphagia lasting < 24 hours; amaurosis fugax (transient monocular blindness); unilateral deficits such as hemiparesis of hemianesthesia lasting 24 hours to 7 days; or stroke. And:

Imaging: Angiography must confirm $\geq 50\%$ diameter reduction.

ASYMPTOMATIC STENOSIS: Arteriogram must show ≥ 80% diameter reduction.

STROKE: Stroke is defined as lasting over one week with significant recovery of neurological function.

OTHER: None.

California

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have classical TIA (with hemiparesis, hemianesthesia, or dysphasia lasting < 24 hours), amaurosis fugax (monocular blindness lasting ≥ 10 minutes), unilateral neurological deficits (such as

hemiparesis, hemianesthesia, or monocular blindness) lasting 24 hours to several days (reversible ischemic neurological deficit or RIND), or stroke. And:

Imaging: Angiography or DSA must demonstrate stenosis of 80% or carotid lesion with ulceration, or CAT scan or MRI must demonstrate silent infarction with stenosis of 80% or carotid lesion with ulceration.

ASYMPTOMATIC STENOSIS: Angiography showing 80% stenosis referred for PA review.

STROKE: Stroke is defined as a stroke lasting over one week with complete or nearly complete recovery of function.

OTHER: Asymptomatic cases in special HCFA study are automatically approved for specified practitioners and providers.

Colorado

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have one of the following: transient monocular blindness (amaurosis fugax) with ipsilateral stenosis or plaque with ulceration; TIA involving the anterior circulation with face, arm, hand, or leg numbness or weakness, aphasia, , or dysphasia for < 24-48 hours traceable to the appropriate carotid; or recent CVA. Additionally, the medical record must document the neurological deficit. And:

Imaging: Arteriogram or DSA must show a hemodynamically significant lesion, defined as at least 60% diameter stenosis, 84% cross sectional area stenosis, or ulceration. Hemispheric symptoms also require a CT scan or MRI.

ASYMPTOMATIC STENOSIS: The patient must have a hemodynamically significant lesion, defined as at least 60% diameter stenosis, 84% cross sectional area stenosis, or asymptomatic severe, deep ulcerative plaque.

STROKE: Stroke is defined as a recent CVA traceable to the extracranial carotid source where the patient made a with functional recovery, but would benefit from protection against a recurrent event in the distribution of the stroke artery. It also includes stroke in progress or acute stroke within 6 hours following carotid endarterectomy or neck trauma.

Connecticut

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have a focal or neurological deficit (transient or permanent) compatible with a carotid lesion. Brain imaging must not reveal a lesion that could explain the clinical findings. And:

Imaging: Angiography must demonstrate $\geq 60\%$ linear stenosis of the internal carotid artery, or significant ulceration of the internal carotid artery with symptoms of cerebrovascular insufficiency compatible with the affected side while on antiplatelet drugs.

ASYMPTOMATIC STENOSIS: Angiography must demonstrate $\geq 90\%$ stenosis of internal carotid artery in the asymptomatic patient.

STROKE: None.

OTHER: None.

Delaware & West Virginia

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have cerebrovascular insufficiency symptoms. And:

Imaging: Angiography must demonstrate $\geq 50\%$ unilateral stenosis of the common or internal carotid, $\geq 50\%$ bilateral stenosis, internal carotid occlusion with $\geq 50\%$ contralateral stenosis, or an ulcerated atheromatous plaque.

ASYMPTOMATIC STENOSIS: Angiography must demonstrate $\geq 80\%$ unilateral internal or common carotid stenosis, $\geq 50\%$ stenosis in the presence of a contralateral internal or common carotid, or total occlusion.

STROKE: None.

OTHER: None.

District of Columbia & Maryland

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have TIA, amaurosis fugax, previous atherothrombotic stroke, stroke-in-evolution, crescendo TIAs, or recurrent

global or non-specific symptoms while on antiplatelet or anticoagulant therapy. And:

Imaging: For TIAs or amaurosis fugax, angiography or duplex imaging must find > 50% diameter ipsilateral common or internal carotid artery stenosis. Or angiography must find a large ulcerative lesion in the ipsilateral common or internal carotid artery. Or for repeated TIAs, angiography must find an occluded ipsilateral internal carotid artery and > 50% diameter ipsilateral external carotid artery stenosis. Or for persistent focal TIAs despite anticoagulant or antiplatelet therapy, angiography must find < 50% common or internal carotid artery stenosis, or a small ulcerative lesion in the ipsilateral common or internal carotid artery.

For previous atherothrombotic stroke, angiography or duplex imaging must find > 50% diameter ipsilateral common or internal carotid artery stenosis. Or angiography must find a large ulcerative lesion in the ipsilateral common or internal carotid artery. On rare occasions it would be appropriate to perform a carotid endarterectomy in a patient with an acute stroke if the operation is performed shortly after the stroke and angiography or duplex imaging finds > 70% diameter ipsilateral common or internal carotid artery stenosis.

For stoke in evolution, angiography or duplex imaging must find > 70% diameter ipsilateral common or internal carotid artery stenosis. Or angiography must find > 50% diameter common or internal carotid artery stenosis and a large multicentric ulcerative lesion in the ipsilateral common or internal carotid artery.

For crescendo TIAs, angiography or duplex imaging must find > 50% diameter common or internal carotid artery stenosis, or < 50% diameter common or internal carotid artery stenosis on the side appropriate to the symptoms with > 50% diameter common or internal carotid artery stenosis on the opposite side. Or angiography must find a large ulcerative lesion in the ipsilateral common or internal carotid artery.

For recurrent global or nonspecific symptoms while on antiplatelet or anticoagulant therapy, angiography must find > 50% diameter common or internal carotid artery stenosis, or a large ulcerative lesion in the common or internal carotid artery.

ASYMPTOMATIC STENOSIS: Angiography or duplex imaging must find > 70% common or internal carotid artery stenosis. Or OPG-Gee must be positive for > 50% diameter common or internal carotid artery stenosis. Or angiography must find a large multicentric ulcerative lesion in the common or internal carotid artery.

STROKE: Stroke includes a patient who has suffered an atherothrombotic stroke. The patient should not have an incapacitating or profound neurologic deficit but

rather is a functional adult living within the community. The neurologic symptoms should have fully stabilized.

OTHER: None.

Florida

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have hemispheric and/or monocular TIAs with an appropriate lesion of the carotid bifurcation, stroke, or global (diffuse or nonfocal) ischemic symptoms with multiple arterial occlusive lesions including high grade stenosis of the internal carotid arteries. And:

Imaging: Noninvasive studies (duplex scanning or other forms of ultrasonic imaging) or arteriography must demonstrated either ≥ 50% carotid stenosis or a nonstenotic ulcerative plaque believed to be the source of cerebral emboli causing the patient's symptoms.

ASYMPTOMATIC STENOSIS: The patient must have $\geq 75-80\%$ carotid stenosis or large carotid ulceration (complex multiple ulcerations) in selected better risk patients.

STROKE: Stroke is defined as a hemispheric completed stroke with good recovery (minimal to modest neurological deficit). Stroke-in-evolution or waxing-and-waning deficit in the presence of an unstable carotid lesion: $\geq 95\%$ stenosis or a highly irregular ulcerated lesion not associated with high grade stenosis.

OTHER: Acute carotid thrombosis following arteriography or carotid endarterectomy if surgery can be performed within 1-2 hours after onset.

Georgia

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have a classical TIA (with hemiparesis, hemianesthesia, or dysphasia lasting < 24 hours), amaurosis fugax (ophthalmic artery unilateral insufficiency to retina due to internal carotid stenosis producing transient loss of vision), unilateral neurological deficits such as hemiparesis or hemianesthesia lasting 24 hours to 7 days (RIND), stroke, or vertebral basilar ischemia (drop attacks). And:

Imaging: The arteriogram must find a 90% carotid lesion, or an 80% carotid lesion with significant ulceration, or a brain CAT scan must indicate a silent infarct with a 90% carotid lesion, or an 80% carotid lesion with ulceration.

ASYMPTOMATIC STENOSIS: The patient must have a bruit with ultrasound evidence of 80% or greater carotid stenosis.

STROKE: Stroke is defined as lasting over one week with complete or nearly complete neurological function.

OTHER: Preparatory procedure prior to performing a carotid subclavian shunt.

Illinois

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have symptoms of carotid system insufficiency (e.g., transient monocular blindness or amaurosis fugax, hemispheric ischemia with weakness of numbness of the limbs or face, or aphasia). And:

Imaging: Angiogram or doppler scan must demonstrate one of the following: > 50% unilateral stenosis of the common or internal carotid, > 50% bilateral stenosis, internal carotid occlusion associated with > 50% contralateral stenosis, or an ulcerated atheromatous plaque in the presence of cerebrovascular insufficiency symptoms.

ASYMPTOMATIC STENOSIS: The patient must have > 70% unilateral internal or common carotid stenosis, or > 50% stenosis with a contralateral internal or common carotid total occlusion.

STROKE: Stroke is not addressed.

OTHER: None.

Indiana

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have "focal" cerebrovascular insufficiency symptoms, such as: amaurosis fugax, tingling limbs or face (paresthesia), paresis or paralysis, hemianopia, or sensory deficit. Or the patient must have cerebrovascular insufficiency symptoms. And:

Imaging: For "focal" cerebrovascular insufficiency symptoms, angiogram must demonstrate an ulcerated atheromatous plaque. For cerebrovascular insufficiency symptoms, angiogram must demonstrate > 50% unilateral stenosis of the common or internal carotid artery, > 50% bilateral stenosis, or a severely ulcerated lesion < 50% stenosis associated with symptoms.

ASYMPTOMATIC STENOSIS: Angiogram must demonstrate > 70% unilateral internal or common carotid stenosis, or 50% stenosis in the presence of a contralateral or common carotid lesion or occlusion.

STROKE: Stroke is not addressed.

OTHER: None.

Iowa

SYMPTOMATIC STENOSIS:

Symptoms: The patient must demonstrate ipsilateral carotid territory symptoms such as contralateral weakness, clumsiness, paralysis, contralateral numbness, paresthesias, dysarthria, dysphasia, ipsilateral monocular blindness (amaurosis fugax), or contralateral homonymous hemianopia (defective vision affecting the right halves or left halves of the visual fields). And:

Imaging: Angiogram or duplex study must demonstrate $\geq 75\%$ unilateral stenosis of the ipsilateral common or internal carotid, $\geq 50\%$ stenosis of the ipsilateral common or internal carotid associated with contralateral internal carotid artery occlusion, or ulcerated atheromatous carotid bifurcation plaque with associated stenosis $\geq 50\%$.

ASYMPTOMATIC STENOSIS: Asymptomatic stenosis is not mentioned.

STROKE: Stroke is not addressed.

OTHER: None.

Kansas

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have (1) a symptom (transient speech dysfunction, altered body sensations, gait disturbance, dysarthria, sudden blindness, transient hemiparesis, or stroke), and (2) a sign (carotid bruit, neurological examination confirming deficits, or cholesterol plaques in the eye grounds). And:

Imaging: Angiography must confirm an atherosclerotic lesion in the appropriate carotid artery.

ASYMPTOMATIC STENOSIS: Arteriogram must diagnose a 30% carotid lesion or a carotid lesion with ulceration, or brain CAT scan must demonstrate a silent infarct with a significant carotid lesion.

STROKE: Stroke is defined as a stroke with complete or nearly complete recovery of neurological function.

OTHER: None.

Kentucky

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have either focal cerebrovascular insufficiency symptoms such as amaurosis fugax, tingling limbs or face (paresthesia), paresis or paralysis, hemianopia, or sensory deficit; or general cerebrovascular insufficiency symptoms. And:

Imaging: For focal cerebrovascular insufficiency symptoms, angiogram or arterial DSA must demonstrates an ulcerated atheromatous plaque. For general cerebrovascular insufficiency symptoms, angiogram or arterial DSA must demonstrates an ulcerated atheromatous plaque, > 50% unilateral stenosis of the common or internal carotid artery, > 50% bilateral stenosis, or a severely ulcerated lesion with < 50% stenosis.

ASYMPTOMATIC STENOSIS: Angiogram or arterial DSA must demonstrate > 70% unilateral internal or common carotid stenosis, or 50% stenosis in the presence of a contralateral or common carotid lesion or occlusion.

STROKE: Stroke is not addressed.

OTHER: None.

Louisiana

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have TIA, CVA, syncope; sudden onset of focal weakness, disorientation, dimming of vision, or monocular loss of vision; episodic sensation of or loss of consciousness or episodic confusion or amnesia; sensory loss; or episodic dysarthria or dysphagia. And:

Imaging: Radiography must evidence > 70% stenosis of the carotid artery with or without an ulcerative plaque, or sonography must evidence significant stenosis in patients with documented severe allergic reaction to iodinated dyes.

ASYMPTOMATIC STENOSIS: Asymptomatic stenosis is not mentioned.

STROKE: Stroke is identified as a CVA.

OTHER: None.

Maine

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have TIAs (motor or sensory), RIND (unilateral weakness lasting > 24 hours and < 48 hours with no fixed neurological deficit and negative CAT scan), amaurosis fugax, CVA, or basilar-vertebral symptoms (at least two of dizziness, syncope, subclavian steal syndrome). And:

Imaging: Doppler, angiography, or DSA must evidence a surgical carotid lesion in a suitable surgical risk patient.

ASYMPTOMATIC STENOSIS: Doppler, angiography, or DSA must evidence bilateral severe (> 75%) stenosis, severe (> 75%) unilateral stenosis with contralateral internal carotid artery occlusion, or severe (> 75%) bilateral internal carotid artery stenosis in selected pre-operative patients. In addition, Doppler, angiography, or DSA must evidence a surgical carotid lesion in a suitable surgical risk patient.

STROKE: Stroke is defined as CVA with recovery.

OTHER: None.

Massachusetts

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have amaurosis fugax (monocular transient loss of vision), CVA, TIA, RIND, or cholesterol emboli to the eye. And:

Imaging: For amaurosis fugax, CVA, TIA, or RIND, arteriography or DSA must demonstrates ulcerated plaque or > 50% diameter stenosis on the brain affected side, or a duplex scan must demonstrate systolic frequency ≥ 6000 Hz or velocity ≥ 1.5 m/sec. For cholesterol emboli to the eye, arteriography or DSA must demonstrates ulcerated plaque.

ASYMPTOMATIC STENOSIS: Arteriograph or DSA must demonstrate $\geq 90\%$ diameter stenosis on the operative side or < 2 mm. residual lumen on the operative side, or duplex scan must demonstrate systolic frequency ≥ 6000 Hz or velocity of ≥ 1.5 m/sec, or the patient is preoperative for a coronary artery bypass graft and arteriography or DSA demonstrates > 70% diameter stenosis on the operative side and 70-100% diameter stenosis on the non-operative side.

STROKE: Stroke is defined as CVA (ischemic) with significant functional recovery.

OTHER: Patient enrolled in NIH's Asymptomatic Carotid Atherosclerosis Study (Toole) or North American Symptomatic Carotid Endarterectomy Study Trial (Barnett) ia an automatic approval.

Michigan

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have either (1) hemispheric symptoms (TIA, recovered stroke, stroke in evolution, loss of speech, confusion, expressive or receptive language problems, unilateral limb weakness, or paralysis) or amaurosis fugax (unilateral vision loss), or (2) non-hemispheric symptoms (dizziness; diplopia; blurred vision; ataxia; drop attacks; or bilateral limb paralysis, weakness, or numbness). And:

Imaging: For hemispheric symptoms, angiography must evidence > 50% stenosis in the ipsilateral internal carotid artery or common carotid artery, and/or unstable ulcerated lesion. For non-hemispheric symptoms, angiography must evidence > 75% stenosis of the common or internal carotid artery.

ASYMPTOMATIC STENOSIS: Angiography must evidence > 80% stenosis of the common or internal carotid artery.

STROKE: Stroke is defined as recovered stroke or stroke in evolution.

OTHER: None.

Minnesota

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have amaurosis fugax, CVA, or TIAs. And:

Imaging: Arteriogram or digital subtraction angiography must indicate ulcerated plaque or > 50% stenosis on the brain-affected side.

ASYMPTOMATIC STENOSIS: Arteriogram or DSA must indicate 80% stenosis, or > 70% stenosis with ulcerated plaque; or arteriogram or DSA must demonstrate less severe stenosis with CT or MRI evidence of silent infarcts on brain-affected side, or cholesterol emboli to the eye.

STROKE: Stroke is defined as CVA (ischemic) with significant functional recovery.

Mississippi

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have stable, focal, ischemic symptoms (TIAs, amaurosis fugax, RIND, and previous atherothrombotic stroke); stable, diffuse, ischemic symptoms; evolving, focal, ischemic symptoms (stroke in evolution or crescendo TIAs); or acute stroke. And:

Imaging: For stable, focal, ischemic symptoms, arteriography or duplex imaging must judge prominent plaque formation in the internal or common carotid artery appropriate to the symptoms; arteriography must judge a large ulcerative lesion in the internal or common carotid artery; or arteriography must judge an occluded internal carotid artery and prominent plaque formation in the external carotid artery appropriate to the symptoms. For stable, diffuse, ischemic symptoms, arteriography or duplex must find > 50% diameter reduction in the common or internal carotid artery bilaterally. For evolving, focal, ischemic symptoms, arteriography or duplex must judge prominent formation in the internal or common carotid artery, or arteriography must judge a large ulcerative lesion in the internal or common carotid artery. For acute stroke, arteriography or duplex imaging must find prominent plaque formation in the internal or common carotid artery and the procedure must be done shortly after the onset of stroke.

ASYMPTOMATIC STENOSIS: Arteriography or duplex imaging must find an atherosclerotic lesion in the common or internal carotid artery producing > 75% diameter reduction, or arteriography must find a large multicentric ulcerative atherosclerotic lesion in the common or internal carotid artery.

STROKE: Stroke is defined as stroke in evolution (which refers to the neurological deficit manifested hours or days after the initial event) and acute stroke (which is a stroke of only several hours duration).

OTHER: A patient may undergo a carotid endarterectomy prior to or in conjunction with another procedure for the purpose of reducing the risk of further stroke.

Missouri

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have TIA or CVA symptoms. And:

Imaging: Radiographic evidence must show > 50% carotid occlusion (diameter), or 70% reduction in the cross-sectional area, or ulcerated plaque, or embolic phenomenon.

ASYMPTOMATIC STENOSIS: Asymptomatic stenosis is not mentioned.

STROKE: Stroke is defined as a CVA.

OTHER: None.

Montana & Wyoming

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have classical TIAs with hemiparesis, hemianesthesia, or dysphasia lasting < 24 hours; or amaurosis fugax; or unilateral neurological deficits such as hemiparesis or hemianesthesia lasting 24 hours to 7 days (RIND); or stroke. And:

Imaging: Angiography including DSA must confirm an atherosclerotic lesion in the appropriate carotid artery.

ASYMPTOMATIC STENOSIS: Arteriogram must find a 90% carotid lesion, or an 80% carotid lesion with significant ulceration; or brain CAT scan must find a silent infarct with a 90% carotid lesion, or an 80% carotid lesion with ulceration.

STROKE: Stroke is defined as a stroke lasting over one week with complete or nearly complete recovery of neurological function.

OTHER: None.

Nebraska

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have ipsilateral carotid territory symptoms including contralateral weakness, clumsiness, paralysis, contralateral numbness, paresthesias including loss of sensation, dysarthria, dysphasia, ipsilateral monocular blindness (amaurosis fugax), or contralateral homonymous hemianopia (defective vision affecting the right halves or left halves of the visual fields). And:

Imaging: Angiogram or duplex study demonstrates $\geq 75\%$ unilateral carotid stenosis of the ipsilateral common or internal carotid artery, $\geq 50\%$ stenosis of the common or internal carotid artery associated with contralateral internal carotid artery occlusion, or ulcerated atheromatous carotid bifurcation plaque with associated stenosis of $\geq 50\%$.

ASYMPTOMATIC STENOSIS: Asymptomatic stenosis is not mentioned.

STROKE: Stroke is not addressed.

OTHER: None.

New Hampshire

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have classical TIAs with hemiparesis, hemianesthesia, or dysphasia lasting < 24 hours; or amaurosis fugax; or unilateral neurological deficits such as hemiparesis or hemianesthesia lasting 24 hours to 7 days (RIND); CVA; or symptomatic carotid bruit. And:

Imaging: Arteriography must find a 90% carotid stenosis, or an 80% carotid stenosis with significant ulceration. Noninvasive carotid examination must be confirmed by arteriography.

ASYMPTOMATIC STENOSIS: Asymptomatic stenosis is not mentioned.

STROKE: Stroke is defined as a cerebrovascular accident lasting over one week with complete or partial recovery of neurological function.

OTHER: None.

New Jersey

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have classical TIAs with hemiparesis, hemianesthesia, or dysphasia; or amaurosis fugax; or stroke. And:

Imaging: Angiography including DSA must confirm an atherosclerotic lesion in the appropriate carotid artery

ASYMPTOMATIC STENOSIS: Arteriogram must reveal $\geq 80\%$ carotid stenosis (complex ulcerations with < 80% stenosis require referral).

STROKE: Stroke is defined as the patient having complete or nearly complete recovery of neurological function.

New Mexico

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have a mild or fluctuating neurological deficit with correspondence of symptoms/signs to the hemispheric distribution of the obstructed carotid artery. And:

Imaging: Angiography or DSA must demonstrate $\geq 70\%$ stenosis of the internal carotid artery, carotid bulb, or common carotid artery (or 50% with a large ulcer).

ASYMPTOMATIC STENOSIS: Angiography or DSA must demonstrate $\geq 70\%$ stenosis of the internal carotid artery, carotid bulb, or common carotid artery.

STROKE: Stroke is not addressed.

OTHER: Unlike other PRO criteria, New Mexico lists the conditions that determine when the carotid endarterectomy is "usually not indicated." This surgical procedure is not indicated when there is < 50% carotid stenosis without ulcerated plaque, or when a brain imaging procedure documents new, major infarction on the affected side.

New York

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have classical TIA with hemiparesis, hemianesthesia, or dysphasia; or amaurosis fugax; or stroke. And:

Imaging: Angiography including DSA must confirm an atherosclerotic lesion in the appropriate carotid artery.

ASYMPTOMATIC STENOSIS: Arteriogram must reveal $\geq 80\%$ carotid stenosis (complex ulcerations with < 80% stenosis require referral).

STROKE: Stroke is defined as the patient having complete or nearly complete recovery of neurological function.

North Carolina & South Carolina

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have transient speech dysfunction, altered body sensation, gait disturbance, dysarthria; or amaurosis fugax; or transient hemiparesis; or stroke. And:

Imaging: Angiography must demonstrate carotid stenosis $\geq 75\%$; or ulcerated plaque refractory to conservative medical management; or carotid aneurysm, or carotid dissection; or clinical radiography must evidence a prior cerebral stroke in association with an ipsilateral carotid stenosis $\geq 75\%$.

ASYMPTOMATIC STENOSIS: Angiography must demonstrate carotid stenosis ≥ 75%. In addition, the medical record must include a consenting opinion from a non-affiliated second physician stating that the procedure is merited.

STROKE: Stroke is defined as a stroke with complete or nearly complete recovery of neurological function.

OTHER: None.

North Dakota

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have classical TIAs with hemiparesis, hemianesthesia, or dysphasia lasting < 24 hours; or amaurosis fugax; or unilateral neurological deficits such as hemiparesis or hemianesthesia lasting 24 hours to 7 days (RIND); or stroke. And:

Imaging: Angiography including DSA must confirm an atherosclerotic lesion in the appropriate carotid artery.

ASYMPTOMATIC STENOSIS: Arteriogram must find a 90% carotid lesion, or an 80% carotid lesion with significant ulceration; or brain CAT scan must find a silent infarct with a 90% carotid lesion, or an 80% carotid lesion with ulceration.

STROKE: Stroke is defined as a stroke lasting over one week with complete or nearly complete recovery of neurological function.

Ohio

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have cerebrovascular insufficiency symptoms (i.e., TIAs, amaurosis fugax, sensory or motor monoparesis or hemiparesis). And:

Imaging: Angiogram, DSA, or duplex imaging must demonstrate $\geq 50\%$ unilateral cross-sectional stenosis of the common or internal carotid, $\geq 50\%$ bilateral cross-sectional stenosis, or complete ipsilateral internal carotid occlusion associated with $\geq 50\%$ contralateral cross-sectional stenosis (only the contralateral lesion should be considered for surgery), or a large ulcerated plaque.

ASYMPTOMATIC STENOSIS: Angiogram, DSA, or duplex imaging must demonstrate $\geq 75\%$ unilateral internal or common carotid cross-sectional stenosis, or $\geq 50\%$ stenosis in the presence of a contralateral internal or common carotid occlusion.

STROKE: Stroke is defined as documented, ipsilateral stroke.

OTHER: None.

Oklahoma

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have amaurosis fugax (monocular or partial blindness lasting < 10 minutes); or hemispheric TIA with the past 12 months; or hemispheric stroke. And:

Imaging: Angiography or DSA must document > 50% stenosis and/or ulceration in an appropriate carotid artery (i.e., the carotid supplying the cerebral hemisphere responsible for the symptoms). The percentage of stenosis must be specified.

ASYMPTOMATIC STENOSIS: Angiography or DSA must document > 75% stenosis, or lumen < 2 mm in the common or internal carotid artery, or bilateral stenosis with > 75% occlusion on the operative side.

STROKE: Stroke is described as hemispheric stroke with documented good recovery or with minimal to modest deficit.

Oregon

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have amaurosis fugax, hemispheric TIA, or stroke. Or:

Imaging: The patient must have a hemodynamically significant stenosis (50% diameter or 75% cross-sectional area), or an ulcerated plaque.

ASYMPTOMATIC STENOSIS: The patient must have a hemodynamically significant stenosis (50% diameter or 75% cross-sectional area).

STROKE: Stroke is defined as hemispheric stroke with documented good recovery and with minimal to modest deficit.

OTHER: None.

Pennsylvania

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have TIA (speech dysfunction, altered body sensation, gait disturbance, dysarthria, loss of motor coordination of upper or lower extremity, hemiparesis, or uniparesis); or amaurosis fugax, if ipsilateral to lesion; or stroke. And: physical examination must suggest a carotid bifurcation atheroma or embolization by a cervical bruit; neurological deficits; or oculopneumoplethysmography, doppler spectral frequency analysis, or duplex scanning evidencing a significant carotid lesion; ulcerated plaque; or > 70% stenosis. And:

Imaging: Angiography alone, or angiography and doppler spectral scanning (or duplex scanning), must confirm > 70% diameter stenosis.

ASYMPTOMATIC STENOSIS: Angiography must indicate > 70% bifurcation stenosis and the patient has no major operative risk factors which contraindicate surgery. If > 70% stenosis on noninvasive studies, angiography must confirm.

STROKE: Stroke is defined as a stroke with complete or nearly complete recovery of neurological function.

Puerto Rico

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have classical TIAs with hemiparesis, speech dysfunction, altered body sensations, gait disturbance, hemianesthesia, or dysphasia lasting < 24 hours; or amaurosis fugax; or unilateral neurological deficits such as hemiparesis or hemianesthesia lasting 24 hours to 7 days (RIND); or stroke. Physical examination must find carotid bruit, neurological deficits, or cholesterol plaques in the eye grounds. And:

Imaging: Angiography must confirm an atherosclerotic lesion in the appropriate carotid artery.

ASYMPTOMATIC STENOSIS: Arteriogram must find a 90% carotid lesion, or an 80% carotid lesion with significant ulceration; or brain CAT scan must find a silent infarct with a 90% carotid lesion, or an 80% carotid lesion with ulceration.

STROKE: Stroke is defined as a stroke lasting over one week with complete or nearly complete recovery of neurological function.

OTHER: None.

Rhode Island

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have focal or neurological deficit (transient or permanent) compatible with carotid lesion. And:

Imaging: Angiogram must demonstrate ulceration of the internal carotid artery compatible with the affected side while on antiplatelet drugs. Brain CT scan must not reveal another lesion that could explain the symptoms.

ASYMPTOMATIC STENOSIS: Asymptomatic stenosis is not mentioned.

STROKE: Stroke is not addressed.

OTHER: None.

South Dakota

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have transient monocular blindness (amaurosis fugax) with ipsilateral carotid stenosis or plaque; or TIA (involving the anterior

circulation with face, arm, hand, or leg numbness or weakness; aphasia; or dysphasia) for < 24-48 hours and traceable to the appropriate carotid, or stroke. The medical record must document neurological deficit. And:

Imaging: Arteriogram or DSA must show a hemodynamically significant lesion defined as at least 60% diameter stenosis or 84% cross sectional area stenosis or ulceration. Hemispheric symptoms (transient focal motor sensory or aphasias) require a CT scan or MRI.

ASYMPTOMATIC STENOSIS: Imaging must demonstrate stenosis ≥ 60% diameter or 84% cross-sectional area, or a severe, deep ulcerative plaque.

STROKE: Stroke is defined as a recent CVA traceable to the extra-cranial carotid source where the patient made a functional recovery but would benefit from protection against a recurrent event. Additional stroke definitions include a stroke in progress or acute stroke within 6 hours following carotid endarterectomy or trauma to the neck.

OTHER: None.

Tennessee

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have classical TIAs with hemiparesis, hemianesthesia, or dysphasia lasting < 24 hours; or amaurosis fugax (temporary loss of vision in one eye due to insufficient blood flow to the retina and lasting < 10 minutes); or unilateral neurological deficits such as hemiparesis or hemianesthesia lasting 24 hours to 7 days (RIND); or stroke. And:

Imaging: Arteriogram must find a $\geq 90\%$ carotid lesion, or a $\geq 80\%$ carotid lesion with significant ulceration; or brain scan must find a 90% carotid lesion, or an 80% carotid lesion with ulceration.

ASYMPTOMATIC STENOSIS: Imaging must find a $\geq 90\%$ carotid lesion, a 80% carotid lesion with significant ulceration, silent infarct with a $\geq 90\%$ carotid lesion, or silent infarct with a $\geq 80\%$ carotid lesion with ulceration.

STROKE: Stroke is defined as a stroke lasting over one week with complete or nearly complete recovery of neurological function.

Texas

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have definite TIA or stroke involving the ipsilateral hemisphere or ipsilateral retinal circulation. And:

Imaging: Imaging must find > 50% stenosis of the carotid artery or an ulcerated plaque.

ASYMPTOMATIC STENOSIS: Imaging must find significant stenosis (> 90%) in the common or internal carotid artery, or stenosis > 50% in the common or internal carotid artery with the presence of an ulcerated plaque.

STROKE: Stroke is defined as a non-disabling stroke involving the ipsilateral hemisphere or ipsilateral retinal circulation.

OTHER: None.

Utah

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have classical TIAs with hemiparesis, hemianesthesia, or dysphasia lasting < 24 hours; or amaurosis fugax (transient loss of vision); or unilateral neurological deficits such as hemiparesis or hemianesthesia lasting 24 hours to 7 days; or stroke. And:

Imaging: Angiography, including four-vessel intra and extracranial direct arteriogram, must confirm the appropriate carotid lesion and lack of significant distal obstructive disease.

ASYMPTOMATIC STENOSIS: Asymptomatic stenosis is not mentioned.

STROKE: Stroke is defined as a stroke lasting over one week with complete or nearly complete recovery of neurological function.

OTHER: None.

Vermont

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have classical TIAs (i.e., hemiparesis, hemianesthesia, or dysphasia lasting < 24 hours); or amaurosis fugax (transient

monocular blindness); or unilateral neurological deficits such as hemiparesis or hemianesthesia lasting 24 hours to 7 days (RIND); or stroke. And:

Imaging: Angiography must find $\geq 70\%$ stenosis in the appropriate carotid artery.

ASYMPTOMATIC STENOSIS: CT scan must find silent infarct. Angiography must find at least 70% stenosis in appropriate carotid artery.

STROKE: Stroke is defined as a stroke lasting over one week with complete or nearly complete recovery of neurological function.

OTHER: None.

Virginia

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have focal or global cerebrovascular insufficiency symptoms or signs including amaurosis fugax (temporary, reversible loss of vision), unilateral transient tingling in limbs or face (paresthesias), paresis, paralysis, diplopia (double vision), vertigo, TIA, focal neurological deficit that resolves in < one hour, stroke, syncope, gait disturbance, dysarthria, transient speech dysfunction, or altered body sensations. And:

Imaging: Angiography must evidence > 50% plaque stenosis of common or internal carotid artery; or plaque necrosis or ulceration (e.g., actively embolic); or a totally occluded internal carotid artery with > 70% stenosis in the external carotid artery.

ASYMPTOMATIC STENOSIS: Angiography must evidence > 80% plaque stenosis.

STROKE: Stroke is defined as a completed stroke over 6 weeks old or fewer than 18 months old.

OTHER: None.

Virgin Islands

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have cerebral vascular insufficiency symptoms. And:

Imaging: Angiogram must demonstrate: > 50% unilateral stenosis of the common or internal carotid, or > 50% bilateral stenosis, or internal carotid

occlusion associated with > 50% contralateral stenosis, or an ulcerated atheromatous plaque.

ASYMPTOMATIC STENOSIS: Angiogram must demonstrate > 70% unilateral internal or common carotid stenosis, or > 50% stenosis in the presence of a contralateral internal or common carotid (occlusion), or total occlusion.

STROKE: Stroke is not addressed.

OTHER: None.

Wisconsin

SYMPTOMATIC STENOSIS:

Symptoms: The patient must have TIAs, or amaurosis fugax, or RIND (e.g., tingling limbs, face paresthesias, paresis, or paralysis), or nonhemispheric symptoms (e.g., vertigo, syncope). The symptoms must be consistent with the lesion location. And:

Imaging: Angiogram must confirm carotid stenosis > 70% or an ulcerated atheromatous plaque.

ASYMPTOMATIC STENOSIS: Angiogram must demonstrate > 70% stenosis; and carotid duplex scan must document blood velocity > 1.5 m/sec, or peak systolic frequency > 12 kilohertz, or reversed periorbital flow.

STROKE: A physician advisor must review the patient's stroke (CVA) history.