Management of Carotid Atherosclerosis

MEDICARE EVIDENCE DEVELOPMENT AND COVERAGE ADVISORY COMMITTEE MEETING

JANUARY 25, 2012

CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF CLINICAL STANDARDS AND QUALITY
COVERAGE AND ANALYSIS GROUP
DIVISION OF MEDICAL AND SURGICAL SERVICES

Current Medicare Coverage

- Best Medical Therapy (BMT)
  - Drug coverage under Part D
- Carotid Endarterectomy (CEA)
  - No national coverage determination (NCD)
  - Coverage for CEA is at local Medicare contractor discretion
- Carotid Artery Stenting (CAS) - *NCD Manual Section 20.7*
  - Medicare covers CAS in FDA approved Category B IDE trials
  - Medicare covers FDA approved carotid stents when used with FDA approved or cleared embolic protection devices for FDA approved indications when furnished in FDA approved post approval studies

Current Medicare Coverage (con't)

- CAS (con't)
  - Medicare covers CAS with embolic protection in patients at high risk for adverse events from CEA:
    - In symptomatic patients with ≥ 70% stenosis
    - In symptomatic patients with 50-70% stenosis when procedures are performed in FDA approved Category B IDE trials, FDA approved post approval studies or as a routine cost under the clinical trials policy
    - In asymptomatic patients with ≥ 80% stenosis when procedures are performed in FDA approved Category B IDE trials, FDA approved post approval studies or as a routine cost under the clinical trials policy

Primary Focus of this Meeting

- Whether or not carotid artery stenting (CAS), carotid endarterectomy (CEA) and best medical therapy (BMT) improve outcomes in symptomatic and asymptomatic persons with carotid atherosclerosis
- CMS is most interested in stroke prevention
- Outcomes of interest are stroke (all stroke) and death (all cause mortality)
- CMS is also seeking panel input on whether or not published evidence for these strategies is generalizable to the Medicare population – for both men and women, and persons of different racial/ethnic backgrounds.

Definitions

- Symptomatic means:
  - The presence or absence of focal signs or symptoms of a transient ischemic attack (reversible and lasting < 24 hours),
  - Amaurosis fugax (sudden loss of vision in one eye), or
  - An ischemic stroke in either cerebral hemisphere.
- Asymptomatic means the absence of all these events.

Voting Scale

- For the voting questions, use the following scale identifying level of confidence:
  - 1 represents the lowest or no confidence
  - 3 represents intermediate confidence
  - 5 represents a high level of confidence

1 Low Confidence		3 Intermediate		5 High Confidence

Voting Question 1

How confident are you that there is adequate evidence to determine if persons in the Medicare population who are asymptomatic for carotid atherosclerosis can be identified as being at high risk for stroke in either cerebral hemisphere?

Discussion: If there is at least intermediate confidence (score ≥ 2.5), are there ethical concerns to conducting RCTs of CAS/CEA/BMT in the general asymptomatic population? Would such trials only be appropriate for those identified to be at high risk for stroke?

Voting Question 2

How confident are you that there is adequate evidence to determine if persons in the Medicare population, who are considering carotid revascularization, can be identified as being at high risk for adverse events from CEA?

Discussion: If there is at least intermediate confidence (score ≥ 2.5), how does one reliably (across medical and surgical specialties) identify these individuals?

Voting Question 3

For persons with symptomatic carotid atherosclerosis and carotid narrowing (≥ 50% by angiography or ≥ 70% by ultrasound) who are not generally considered at high risk for adverse events from CEA:

a. How confident are you that there is adequate evidence to determine whether or not either CAS or CEA is the favored treatment strategy, as compared to BMT alone, to decrease stroke or death in the Medicare population?

b. If there is at least intermediate confidence (score ≥2.5), how confident are you that:

Voting Question 3 (con't)

i. CAS is the favored treatment strategy in this population?
ii. CEA is the favored treatment strategy in this population?
iii. BMT alone is the favored treatment strategy in this population?

Discussion: If there is at least intermediate confidence (score ≥ 2.5), for questions 3.b.i, ii or iii above, please discuss the impact of the following on your conclusions:

i. Patient age, gender, and racial/ethnic background
ii. Time to treatment, e.g., < 2 weeks or > 2 weeks from onset of symptoms.

Voting Question 4

For persons with asymptomatic carotid atherosclerosis and carotid narrowing (≥ 60% by angiography or ≥ 70% by ultrasound) who are not generally considered at high risk for adverse events from CEA:

a. How confident are you that there is adequate evidence to determine whether or not either CAS or CEA is the favored treatment strategy, as compared to BMT alone, to decrease stroke or death in the Medicare population?

b. If there is at least intermediate confidence (score ≥ 2.5), how confident are you that:

Voting Question 4 (con't)

i. CAS is the favored treatment strategy in this population?
ii. CEA is the favored treatment strategy in this population?
iii. BMT alone is the favored treatment strategy in this population?

Discussion: If there is at least intermediate confidence (score ≥ 2.5), please discuss the impact of the following on your conclusions:

i. Patient age, gender, and racial/ethnic background (for 4.b.i, ii or iii)
ii. Concurrent BMT (for 4.b.i or ii).

Voting Question 5

For persons with asymptomatic carotid atherosclerosis who are not generally considered at high risk for stroke in either cerebral hemisphere:

a. How confident are you that there is adequate evidence to determine whether or not CAS or CEA or BMT alone is the favored treatment strategy to decrease stroke or death in the Medicare population?

b. If there is at least intermediate confidence (score ≥ 2.5), how confident are you that:

Voting Question 6

In the general Medicare population:

a. How confident are you that there is adequate evidence to determine whether or not carotid artery screening of asymptomatic persons decreases stroke or death?
b. If there is at least intermediate confidence (score ≥ 2.5), how confident are you that carotid artery screening of asymptomatic persons decreases stroke or death?

Discussion Question 7

What unmet research needs, specific to the following issues, are important to consider and explore further?

a. Should future stroke prevention trials:
   i. Be powered to evaluate only symptomatic or asymptomatic patients?
   ii. Be powered to draw conclusions regarding gender?
   iii. Evaluate outcomes for more racially/ethnically diverse patient populations?

Voting Question 5 (con't)

i. CAS is the favored treatment strategy in this population?
ii. CEA is the favored treatment strategy in this population?
iii. BMT alone is the favored treatment strategy in this population?

Discussion: If there is at least intermediate confidence (score ≥ 2.5), please discuss the impact of the following on your conclusions:

i. Patient age, gender, and racial/ethnic background (for 5.b.i, ii or iii)
ii. Concurrent BMT (for 5.b.i or ii).

Discussion Question 7 (con't)

b. So as to help delineate those who require carotid revascularization from those who do not, how should future trials best utilize and validate, for the Medicare population, the following tools to identify persons with asymptomatic carotid atherosclerosis who are at high risk for stroke?
   i. Advanced imaging, such as 3D ultrasound, for plaque morphology
   ii. Transcranial Doppler (TCD) for cerebral microembolization
   iii. Pre- and post-procedure diffusion weighted MRI (DW-MRI) for silent infarcts
   iv. Risk assessment tools and predictive stroke models.

Contact Information

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