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Society of Interventional Radiology
The vision to heal

February 10, 2023

Sarah Fulton, MHS, Lead Analysts
Joseph Hutter, MD, Lead Medical Officer
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, Maryland 21244

RE: Reconsideration of NCD 20.7 for percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting

Dear Ms. Sarah Fulton and Dr. Hutter:

The Society of Interventional Radiology (SIR) is a nonprofit, professional medical society representing approximately 8,000 practicing interventional radiology physicians, trainees, students, scientists, and clinical associates, dedicated to improving patient care through the limitless potential of image-guided therapies including experts in the treatment of carotid artery disease. Our members represent the majority of practicing vascular and interventional radiologists in the United States. The SIR appreciates the opportunity to comment on the National Coverage Determination (NCD) 20.7: for percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting.

Patient Selection

The Society of Interventional Radiology has previously stated (4/15/2009) its support for expanded coverage for carotid artery stenting (CAS) based on the data from CAPTURE 2 and EXACT (Gray et al) and comparisons of CAS and CEA based on national hospital reported outcomes (McPhee et al) and the Society for Vascular Surgery Vascular Registry (Sidawy et al). Since the prior NCD, the SIR has monitored developments in the literature and additional outcomes have been published that support equipoise between CEA and CAS, thus supporting broader patient selection for CAS reimbursement.

CREST evaluated the safety and efficacy of CAS and CEA in symptomatic and asymptomatic patients with average surgical risk and showed no significant difference between CAS and CEA for a primary composite endpoint of periprocedural stroke, myocardial infarction, and death at 30 days. Procedural stroke and death and ipsilateral stroke were not significantly different at 4 years follow-up, and ipsilateral stroke was not significantly different at 10 years. When the outcomes were stratified by symptomatic status, again there were no differences between CAS vs. CEA for the primary endpoint (Brott el al, Brott et al, Hopkins et al, and Silver et al). The ACT-1 Trial randomized asymptomatic patients to CAS or CEA, and, similar to CREST, CAS was noninferior to CEA for a primary composite endpoint of stroke, myocardial infarction, and death at 30 days (Rosenfield et al). Another randomized trial, SPACE-2, showed no difference between CAS and CEA for stroke and death at 30 days and at 1 year (Reiff et al). Most recently ACST-2 has also shown comparable results (Halliday et al) for CEA and CAS.

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Based on this expanded body of clinical evidence, SIR supports updating NCD 20.7 to broaden Medicare beneficiary access to PTA and CAS. Patient selection criteria should be expanded to reflect these results and mirror CEA access by including patients at standard surgical risk, patients with symptomatic carotid artery stenosis ≥50%, and patients with asymptomatic carotid artery stenosis of ≥70%.

Facility and Operator Requirements

Given broad clinical experience and multiple trials and scientific evidence supporting CAS since the 2009 NCD, SIR recommends removal of operator and facility requirements including mandating data collection as a facility criterion for CAS. We suggest these be handled by the local facility through processes such as peer review, patient safety or quality improvement committees/conferences, random case review, or as part of facility accreditation as a stroke center or CAS center. This change would be in line with other well-established procedures as well as guidelines and recommendations for physician training, operator requirements and facility requirements that have been developed by multiple medical specialty societies.

We thank CMS for consideration of expanded reimbursement for CAS. If we can provide any additional information or if you have any questions, please do not hesitate to contact Keith M. Hume, SIR Executive Director, at khume@sirweb.org.

Sincerely,

Parag J. Patel, MD, FSIR
President, Society of Interventional Radiology

Cc. Keith M. Hume
Executive Director, Society of Interventional Radiology

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