

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S3-02-01
Baltimore, Maryland 21244-1850



Office of Clinical Standards and Quality

Sidney M. Wolfe, MD
Director
Public Citizen's Health Research Group
100 20th Street NW
Washington, DC 20009

Dear Dr. Wolfe:

Thank you for your letter concerning the national coverage determination (NCD) for intracranial stenting and angioplasty (Medicare NCD Manual section 20.7, B5). Since November 2006, Medicare coverage is "for the treatment of cerebral artery stenosis $\geq 50\%$ in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials." We are not aware of any currently enrolling clinical trials that fulfill this requirement.

We are familiar with the concerns that were brought to light during the SAMMPRIS trial and described in detail in the 2011 New England Journal of Medicine article by Chimowitz et al. We are also aware that the Food and Drug Administration (FDA) is currently reviewing the safety and effectiveness of the Wingspan stent system and convened an advisory committee meeting to discuss these issues on March 23, 2012.

Since the current NCD refers explicitly to coverage in FDA-approved protocols, we would not expect further Medicare claims to be submitted if there are no more FDA-approved Category B IDE clinical trials. We plan to consider our options again after FDA has published its decision.

Thank you for your interest in the Medicare program.

Sincerely,

A handwritten signature in black ink, appearing to read "Louis Jacques". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Louis Jacques, MD
Director, Coverage and Analysis Group
Office of Clinical Standards and Quality
Centers for Medicare and Medicaid Services

Cc: Sarah Sorscher, JD, MPH
Michael A. Carome, MD