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

Center for Clinical Standards and Quality
Coverage and Analysis Group

Jack L. Cronenwett, M.D. 09/01/2016
Medical Director, SVS PSO

Dear Dr. Cronenwett:

The Centers for Medicare & Medicaid Services has reviewed the study protocol for the SVS VQI TransCarotid Revascularization Surveillance Project (VQI-TCAR) as well as the FDA acknowledgement recognizing this study as scientifically valid. Accordingly, CMS believes that the VQI-TCAR Surveillance Project should return clinically relevant data. Based on this information, CMS has determined that patients participating in the VQI-TCAR Surveillance Project are included in the currently covered population of patients participating in FDA-approved post approval studies (Pub. 100-3, 20.7, B3).

Because this trial is covered under a national coverage determination, the process does not require study sites to get approval from the Medicare Administrative Contractors. For billing purposes, facilities and providers will submit claims for the TCAR surveillance project using National Clinical Trial (NCT) identifier, NCT02850588.

To facilitate the Medicare payment process, you should provide your study sites with appropriate billing instructions. These include entering the NCT identifier from the ClinicalTrials.gov website on Medicare claims along with the other codes and modifiers provided in the NCD claims processing instructions.

Please contact Sarah Fulton at sarah.fulton@cms.hhs.gov or (410)786-2749 with any additional questions.

Sincerely,

X 

Signed by: Joseph S. Chin -A
Joseph Chin, MD, MS
Deputy Director, Coverage and Analysis Group