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

Jens Eldrup-Jorgensen, MD
SVS PSO Medical Director

05/31/2022

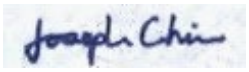
Dear Dr. Eldrup-Jorgensen:

Thank you for sharing the protocol revisions adding standard surgical risk patients to the SVS VQI TransCarotid Revascularization Surveillance Project (VQI-TCAR) with the Centers for Medicare & Medicaid Services (CMS). CMS has determined that patients participating in the VQI-TCAR Surveillance Project, including the new population at standard surgical risk, continue to be included in the currently covered population of patients participating in FDA-approved post approval studies (Pub. 100-03, 20.7, B3).

As noted in the 09/01/2016 letter originally confirming coverage, 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.

Sincerely,

X 

Joseph Chin, MD, MS
Dep Dir, Coveraeg and Analysis Group
Signed by: PIV