SILKROAD MEDICAL®
1213 INNSBRUCK DR., SUNNYVALE, CA 94089 WWW.SILKROADMED.COM

January 13, 2023

Centers for Medicare & Medicaid Services
Central Building - 7500 Security Blvd.
Baltimore, MD 21244
Email: medcacpresentations@cms.hhs.gov , Tara.Hall@cms.hhs.gov

RE: MEDCAC CED Written Comments

Dear Ms. Hall,

Silk Road Medical, a medical device company focused on reducing the risk of stroke and its devasting impact, appreciates the opportunity to provide comment for the MEDCAC CED meeting on February 13-14, 2023. As the developers of a new approach for the treatment of carotid artery disease called TransCarotid Artery Revascularization (TCAR), we have worked collaboratively with CMS, FDA, and the Society of Vascular Surgery Patient Safety Organization (PSO) to develop on-going real-world evidence through the Vascular Quality Initiative – Carotid Artery Stenting (CAS) registry.

Since September 1, 2016, CMS has approved the SVS VQI TransCarotid Revascularization Surveillance Project (VQI-TSP) as an FDA-approved post approval study under the National Coverage Determination 20.7. As a result of the VQI-TSP, numerous peer-reviewed studies, including comparative and cohort studies, have been published to support the safety, efficacy, and effectiveness of TCAR.

Below is our specific suggested revision for Requirement H:

Tag for Requirement	**Revised Proposed Requirements Presented to Key Informants (KIs) (version 2a)**	**Final Proposed Requirements after Public Comments (version 3b)**	**Silk Road Medical Public Comment - Recommendation for Final Proposed Requirements**
Generalizable	J. When feasible and appropriate for answering the CED question, data for the study should come from the real-world practice of medicine including from practitioners diverse in experience and diverse sites of care delivery.	H. When feasible and appropriate for answering the CED question, data for the study should come from beneficiaries in their usual sites of care, although randomization to receive the product may be in place.	H. When reasonable and appropriate, study data should come from beneficiaries in real-world settings treated by practitioners and facilities representative of the expected range of experience and volume that are reasonably anticipated for the specific technology.

We believe that the generation of patient outcomes data based on practices with typical physicians in typical settings is important to assure that future Medicare coverage policy developed upon completion of CED is informed by evidence beyond traditional clinical trial designs.

Thank you for your consideration. We are pleased to answer any questions regarding this comment.

Sincerely,

Erica Rogers
CEO, Silk Road Medical
erogers@silkroadmed.com