Dear Medicare Coverage Advisory Committee Members,

- My name is Yajuan Lu, Director of Corporate Reimbursement and Health Policy of Boston Scientific. As one of the world's largest companies dedicated to developing, manufacturing, and marketing less-invasive therapies, Boston Scientific supplies medical devices and technologies to provide Medicare beneficiaries high quality care in many key clinical areas.

- We have had extensive experience with the CED program since its creation, and we are pleased to have the chance to provide input based on that direct experience.

- We believe that CED provides a valuable and appropriate pathway to Medicare coverage for certain technologies, and we agree with many of AHRQ's recommended modifications.

- In considering AHRQ's recommended revisions to the CED criteria, Boston Scientific believes first and foremost that evidence generation should be designed to ensure the appropriate level of rigor to address safety questions and support Medicare beneficiaries' access to innovative technologies to improve health outcomes. Specifically, we support Amended Requirement C, *The rationale for the study is supported by scientific evidence and study results are expected to fill the specified knowledge gap* and Amended Requirement D, *CMS and investigators agree on an evidentiary threshold for the study as needed to demonstrate clinically meaningful differences in key outcome(s) with adequate precision*, with a few modifications.

    - We would recommend allowing the manufacturer and CMS to review the existing evidence and collaboratively develop a "fit-for-purpose" evidence generation strategy to address the specific gaps CMS and the manufacturer identify within the existing evidence base.

    - The subsequent plan would be designed to evaluate and provide evidence regarding the effectiveness of the technology in the Medicare population. While the evidence plan would not require a specific type of study (e.g., randomized controlled trial), it would include research methods rigorous enough to evaluate a technology's effectiveness in the Medicare population. We believe Criteria C and D should explicitly reflect these principles.

- One of the key challenges we have experienced with the program is the lack of definitive timeline or a process to decide when sufficient data has been collected to reach a coverage or noncoverage decision. The lack of certainty on the duration of the studies adds to unpredictability for manufacturers, creating delays in access for patients and providers. We encourage CMS to develop a process through which the clinical community, manufacturers and CMS could collaboratively identify and decide on the endpoints of the studies once sufficient evidence has been collected.

    - For example, Boston Scientific's WATCHMAN Left Atrial Appendage Closure System has been covered under NCD 20.34 since February 2016. WATCHMAN LAAC has been extensively researched, with 10 clinical trials completed, and more than 200,000 devices implanted in patients, the vast majority of whom are Medicare age. The clinical trials have consistently demonstrated the product's safety, effectiveness, and low adverse events. Despite the significant clinical evidence available, the NCD for LAAC has been in

place for over six years and it remains unclear when the CED will end. We believe a process the establishes a clear end point for sufficient evidence and data collection under CED would benefit all stakeholders.

- In conclusion, Boston Scientific appreciates the opportunity to offer our input to the CED evidence generation criteria and the overall program design. We look forward to continued partnership with CMS and other interested parties to improve the CED program.
- Thank you very much.