SCAI
Society for Cardiovascular Angiography & Interventions

August 28, 2023

Submitted electronically via: http://www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Centers for Medicare and Medicaid Services
Attention: CMS–3421-NC
7500 Security Boulevard
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Transitional Coverage for Emerging Technologies (TCET)

Dear Administrator Brooks-LaSure:

The Society for Cardiovascular Angiography and Interventions (SCAI) has dedicated its work to advancing the profession and is the designated society for guidance, representation, professional recognition, education, and research opportunities for invasive and interventional cardiology professionals. For more than 40 years, SCAI has personified professional excellence and innovation globally, fostering a trusted community of more than 5000 members dedicated to medical advancement and lifesaving care for adults and children with cardiovascular disease.

SCAI appreciates the opportunity to comment on this proposed rule. SCAI supports the adoption of a more comprehensive program for device adoption, such as the TCET program. We agree with the use of the Coverage with Evidence Development framework to enhance the collection of the necessary data to confirm the safety and efficacy of these devices after FDA breakthrough device regulatory approval. We are strongly in support of coverage in a concurrent process coordinated with CMS and the FDA. The ability of CMS to provide coverage is important to enhance device innovation by industry and to enhance the health of our patient population.

Pathway Limitations
SCAI is, however, concerned that the typical pathways that TCET will use, such as national coverage decisions, will delay care for Medicare patients. As the process proposes that only devices that have received FDA market authorization may apply, we are concerned that this late opportunity for payment and development may not be sufficient for important technological breakthroughs to survive on the market, especially when research beyond the pivotal trial is needed to prove health outcomes in the Medicare population. Additionally, other novel medical devices that did not request an FDA breakthrough designation but represent a meaningful

improvement in clinical care for Medicare patients should also be considered.

The program as introduced also has limitations. The introduction of only five devices into the program per year is extremely limiting, considering the number of devices that receive FDA breakthrough approval. Additionally, TCET only applies to the limited number of medical devices that can only secure coverage through the existing CED pathway ignoring those important technologies that CMS believes "lack context" in the Medicare population.

Under the current coverage framework, those limited "context" devices are forced to develop a patchwork of coverage through the complicated and burdensome process of working with the local Medicare Administrative Contractors (MACs). Providing temporary coverage for these important devices will accelerate access and support the collection of real-world evidence on use that will inform development of long-term Medicare coverage criteria.

Appropriate Lookback Period for Recently Authorized Breakthrough Products and those Nearing Authorization

We applaud CMS for working to develop the TCET notice. However, there are no defined or required timelines for when TCET will be finalized. This creates uncertainty for manufacturers that are nearing or may have been recently granted FDA authorization through the Breakthrough program. The TCET notice as currently drafted does not address program access for technologies other than those approximately 12 months away from FDA market authorization. SCAI recommends that the final TCET notice include a "lookback" provision to allow TCET eligibility for breakthrough technologies that are FDA market authorized prior to the effective date of the TCET final notice. Additionally, SCAI recommends that CMS explicitly state that technologies nearing FDA market authorization (i.e., within the 12-month window prior to authorization) are allowed to apply to the TCET program.

Ensure Clear Timeline for Review of Benefit Category, Coding, and Payment

SCAI supports transparency in the process between device companies and CMS. We are encouraged by some of the clear process and timelines present in TCET, and we believe TCET can be improved by providing clearer processes for review and determination of benefit category, coding, and payment. The Technology, Coding and Pricing Group (TCPG), as well as the Hospital and Ambulatory Policy Group (HAPG), will be instrumental in facilitating access to innovative medical products through TCET alongside the Coverage and Analysis Group (CAG). We urge CMS to ensure dialogue between and amongst TCPG, HAPG, and CAG to ensure all processes are in place for coverage, coding and payment to proceed under the TCET program. CMS should also set forth clear timelines to ensure coding and payment for the device is in place before an NCD is issued. We also encourage CMS and FDA to allow medical devices or medical supplies that do not appear in the Medical Device and Medical Supply Name and Primary Device Identifier Dataset to be included for adaptation when further consideration is given to efforts aimed at increasing transparency in the future. SCAI recommends that all steps be clearly defined, including timeframes for key activities, in public facing guidance documents.

Request for Specific Stakeholder Input on the Evidence Base and Conditions of Coverage

SCAI commends CMS for exploring ways to increase feedback from the relevant specialty societies and patient advocacy organizations. We applaud CMS for encouraging these organizations to publicly post

on their website any additional feedback or relevant practice guidelines within 90 days of CMS opening the NCD, and to contact CMS when this information has been posted. While we support efforts to expand ways to receive input from these organizations, we believe CMS should include a few process steps to ensure transparency. SCAI recommends CMS notify the manufacturer upon receipt of the additional information, post this information on CMS' website, and allow the manufacturer to provide a response to CMS in a timely manner.

SCAI continues to support the close collaboration which is required by FDA and CMS to enable the improvement in cardiovascular health of our patients via device innovation. The success of a breakthrough device program which can benefit the American public, including CMS eligible patients, can only be achieved by patient access which will require both timely regulatory and coverage pathways.

SCAI appreciates the opportunity to provide comments on this proposed rule for Transitional Coverage for Emerging Technologies and we look forward to continuing working with CMS to address these important issues. If SCAI can be of any assistance as CMS continues to consider and review these issues, please do not hesitate to contact SCAI's director, regulatory affairs, Monica Wright at 202-327-5451 or at mlwright@scai.org if there are any questions or further requests.

Sincerely,

George Dangas, MD, PhD, MSCAI
President