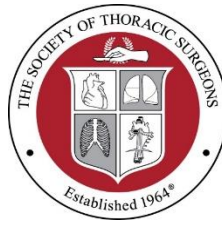


STS Headquarters
633 N Saint Clair St, Suite 2100
Chicago, IL 60611-3658
(312) 202-5800
sts@sts.org



Washington Office
20 F St NW, Suite 310 C
Washington, DC 20001-6702
(202) 787-1230
advocacy@sts.org

August 23, 2023

Chiquita Brooks-LaSure, MPP
Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Medicare Program; Transitional Coverage for Emerging Technologies [CMS-3421-NC]

Dear Administrator Brooks-LaSure,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Transitional Coverage for Emerging Technology (TCET) Notice with Comment. Founded in 1964, STS is a not-for-profit organization representing more than 7,900 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical procedures within the chest.

TCET Pathway-An Opportunity to Accelerate Patient Access to Beneficial Medical Products While Generating Evidence

CMS has developed the TCET pathway to support manufacturers that are interested in working with the agency to generate additional evidence for a device that is appropriate for Medicare beneficiaries and warrants a more expeditious national Medicare coverage.

Working in conjunction with Agency for Healthcare Research and Quality (AHRQ), CMS' goal is to improve coverage with evidence development (CED) to fulfill its potential as a mechanism that simultaneously reduces barriers for innovation while enabling CMS to make more informed coverage decisions for medical devices that improve health outcomes for Medicare beneficiaries.

CMS and AHRQ have made iterative refinements to the CED coverage pathway over time. While CED has generally reduced barriers to innovation and expanded beneficiary access to new technologies and therapies, experiences over the last several years indicates that further improvements can be made to the CED process. CMS believes that certain coverage decisions – in particular, those involving innovative devices – would benefit from a CED framework that establishes a more predictable and transparent approach.

Tying a National Coverage Determination (NCD) to CED requirements can both validate the effectiveness of emerging and innovative therapies and expand access to additional populations

based on ongoing real-world data. It is imperative that any reform to the CED process strike a balance between providing access to innovative technologies and ensuring the collection of robust evidence to inform coverage decisions. The STS believes that it is essential that any reforms to coverage for emerging therapies:

- **Prioritize the collection of real-world data**, particularly for new, innovative medical devices. Data collection creates opportunities to fill post-market evidence gaps and better define patient benefits and risks. While clinical trials provide important information, they often lack generalizability to real-world populations, especially Medicare beneficiaries who are some of the sickest, comorbid patients.
- **Permit early discussions and coordination between the agency and relevant stakeholders** to allow sufficient time for appropriate application, design, and implementation of any CED requirements. This would help physicians, medical specialty organizations, and commercial actors more effectively establish or utilize existing clinical data registries for new CED determinations and incorporate data submission into clinical workflow. It would also make clear who is responsible for different aspects of the CED process.
- **Provide flexibility for data collection mechanisms** to adjust based on new developments in the evidence. New questions can arise during the CED process when the indications for a device expand.
- **Provide registries with timely, cost effective, and continuous access to Medicare claims data** to perform longitudinal studies. Tying Medicare claims data to clinical outcome information enables clinician-led clinical data registries to better track patient outcomes over time, expand their ability to assess the safety and effectiveness of medical treatments, and provide patients with the information necessary to assess the cost-effectiveness of alternative therapies. While CMS refers researchers to the Research Data Assistance Center (“ResDAC”) process, it is limited to narrowly defined research questions and is slow, costly, and cumbersome.

General Principles

CMS’ goal is to finalize an NCD for technologies accepted into and continuing in the TCET pathway, within 6 months after Food and Drug Administration (FDA) market authorization. The TCET pathway builds on prior initiatives, including CED.

STS appreciates CMS’ goal of increasing access to breakthrough therapies but has some concerns about the lag time between FDA approval and the TCET pathway. STS supports a pathway that would bring innovative technology to Medicare beneficiaries as quickly as possible. Previous coverage of breakthrough technologies through an NCD began immediately following FDA approval. However, it is necessary that any new coverage pathway that would provide access to breakthrough technologies needs to be subject to certain guidelines to ensure patient safety and optimize patient outcomes.

If CMS determines that further evidence development (that is, CED) is the best coverage pathway, CMS will work with the manufacturers to reduce the burden on manufacturers, clinicians and patients while maintaining rigorous evidence requirements.

The collection of real-world evidence is a powerful tool to help ensure that innovative technology remains safe and effective. However, there is a cost associated with the CED process. Abstracting data from medical records and inputting it into a registry requires hospital resources. Large databases require significant upkeep and large expense outlays to maintain high fidelity data. For example, technology platforms must be maintained and ensure compliance for Protected Health Information. Additionally, statistical analytic teams are required to analyze and develop reports on the data and independent external audits help validate the quality and accuracy of the data.

Although there is cost for CED participants, STS believes the need and benefits of real-world evidence far outweigh the burdens associated with collecting the data and is necessary for determining appropriateness of care for patients. Relative to other FDA approvals, breakthrough medical device designation requires less evidence of effectiveness for initial approval. As such, we maintain that, in most cases, these devices will need careful monitoring in real world populations. While STS appreciates and shares CMS' goal of reducing burden on stakeholders through collaboration, we believe this should not compromise the collection of robust real-world evidence. The goal of data burden reduction should be secondary to successful data collection.

CMS does not believe that an NCD that requires CED as a condition of coverage should last indefinitely, including under the TCET pathway. If the evidence supports a favorable coverage decision under CED, coverage will be time-limited to facilitate the generation of sufficient evidence to inform patient and clinician decision making and a Medicare coverage determination.

STS strongly cautions against CMS employing hard and fast deadlines for an NCD requiring CED. While a question may be addressed in CED for a certain device and procedure, FDA could expand the indication for the device to be used in a different manner than it was originally tested. This would raise additional questions requiring more evidence collection to address unique and clinically relevant issues in a new patient population with a different need for addressing the reasonable and necessary standard. For example, in 2012 CMS published an NCD for transcatheter aortic valve replacement (TAVR) that contained a CED requirement. In 2019, the TAVR CED was reconsidered. At that time, data collected using the STS and American College of Cardiology (ACC) Transcatheter Valve Therapy (TVT) Registry™ showed evidence supportive of TAVR for specific patient populations but the indications for TAVR were still changing, requiring continued CED to track the incidence of paraventricular regurgitation, the need for permanent pacemaker implantation, and the long-term durability of replacement valves. STS analysis showed that gaps in the evidence base led to uncertainty about the overall impact of TAVR on beneficiary outcomes if furnished outside of the setting of evidence development or clinical trial protocols, and so at the time of the CED reconsideration, additional data collected was needed.

Procedures for the TCET Pathway

Evidence Development Plan (EDP)

Where evidence gaps are identified by CMS and/or AHRQ during the Evidence Preview, the manufacturer should submit an evidence development plan (EDP) to CMS that sufficiently addresses the gaps.

As a rule, it may be appropriate for CMS to consider collaboration/engagement with professional specialty societies that have resources (i.e., registries) that could assist in the development of an EDP. Societies often have relevant insight in terms of evidentiary gaps depending on the device or procedure, as evidenced by the STS/ACC TVT Registry example above.

EDP Submission Timing, EDP Meeting and Finalization of the EDP

Manufacturers are strongly encouraged to begin developing a rigorous proposed EDP as soon as possible after receiving the finalized Evidence Preview due to the tight timeframes needed to effectuate CMS' goal of finalizing a TCET NCD within 6 months after FDA market authorization. Further, to meet the goal of having a finalized EDP approximately 90 business days after FDA market authorization, the manufacturer is encouraged to submit an EDP as soon as possible after FDA market authorization.

Upon receipt of the EDP from the manufacturer, CMS will have 30 business days to review the proposed EDP and provide written feedback to the manufacturer. During this time, CMS will collaborate with AHRQ to evaluate the EDP to ensure it meets established standards of scientific integrity and relevance to the Medicare population. CMS will share consolidated feedback by email and schedule a meeting, which may also include AHRQ, to discuss any recommended refinements and address any questions with and by the manufacturer.

STS has general concerns over the proposed timeline for the TCET pathway. It is unclear that EDP submission timing, meeting, and finalization, all of which require engagement with CMS over evidence, are realistic. CMS notes in the Notice with Comment that the anticipated timeline may take longer if there is conflicting evidence or a novel process during the evidence development review. This is further compounded by the pre-market portion of TCET occurring simultaneously as when manufacturers are going through the FDA approval process. **STS encourages CMS to be forthcoming with realistic timelines for the TCET process.** As we have mentioned, CMS needs to strike the right balance between providing access to emerging technologies without unnecessary delays, and appropriately ensuring the necessary evidence development.

Stakeholder Input

CMS strongly encourages expert input and recommended conditions of coverage (with special attention to appropriate beneficiary safeguards) from relevant specialty societies and patient advocacy organizations. CMS encourages these organizations to publicly post on their website

any additional feedback, including relevant practice guidelines, within 90 days of CMS's opening of the NCD, and to notify CMS when recommendations have been posted.

STS supports the involvement and input requested from relevant specialty societies. As mentioned above, specialty societies can often provide expertise and resources to identify knowledge gaps and the tools for real-world evidence collection.

Transition to Post-TCET Coverage

Updated Evidence Review

CMS states its intention to conduct an updated evidence review within 6 calendar months of the review date specified in the EDP. Following this CMS will conduct quality assurance on the contractor review and assess whether the evidence is sufficient to reach the reasonable and necessary standard.

STS cautions against the proposed 6-month timeframe to conduct an updated evidence review, which is an arbitrary timeline, and in some cases, will be insufficient to collect and provide the necessary evidence. As an example, the STS operates 5 registries all of which require different timeframes to harvest and analyze data. To harvest data from the Adult Cardiac Surgery Database and provide an analysis to participants, it takes roughly 5 months after the last case collected. For this registry, the full 2022 calendar year analysis results were made available to participants in May 2023. Results from the General Thoracic Surgery Database take 8-9 months to analyze. **A more appropriate and feasible timeline would allow 12 months to conduct an analysis from the review date specified in the EDP.**

Additionally, until a decision to end a CED requirement is confirmed, data collection should continue even after the harvest/publication date. A request for an updated evidence review does not guarantee the end of a CED and the need for data collection may continue. In that case, there would be gaps in knowledge during the 6 months (or longer) when the evidence review process is taking place, which may have negative consequences. **No matter what timeline for the updated evidence review CMS determines appropriate, data collection should continue until a final determination has been made.**

Final Decision

If and when it is appropriate, CMS will open an NCD reconsideration by posting a proposed decision which proposes one of the following outcomes:

- (1) an NCD without evidence development requirements;*
- (2) an NCD with continued evidence development requirements;*
- (3) a non-coverage NCD; or*
- (4) permitting local MAC discretion to make a decision*

STS supports the proposed outcomes to an NCD reconsideration. Specifically, we appreciate the recognition that circumstances may warrant an NCD with continued evidence development requirements. As we detailed above, there are times when an indication for a device is changed, and further data collection is required to ensure reasonable and necessary coverage. We believe

the more data we can collect on the functionality of devices in various patient populations, the more providers can make the best decisions for their patients.

Prioritizing Requests

CMS intends to:

- *Review TCET pathway nominations and respond within 30 days after receipt of a nomination email, and*
- *Prioritize innovative medical devices that, as determined by CMS, have the potential to benefit the greatest number of individuals with Medicare.*

Due to resource constraints, CMS anticipates accepting up to five TCET candidates annually.

STS has concerns over the limitation on how many TCET candidates are accepted annually, due in part to the limited resources in the CMS Coverage and Analysis Group.

The underlying goal of the TCET pathway is to bring more clarity and certainty to an otherwise unpredictable process. Accepting such a limited number of candidates fundamentally undermines that goal.

If CMS plans to move forward with the TCET pathway as proposed, we believe there is a need for more resources and expertise to expand its capacity. We understand that CMS must find the correct balance between allocating available resources to existing programs and prioritizing devices to be accepted into the TCET pathway. Yet such a small program surely does not match the significant need that exists, and the benefits to patients that could be provided through quicker access to more innovative therapies. If a more robust approach is not possible in the short term, the agency should clearly state their intent to significantly expand this pathway in future years. In the short term, we encourage CMS to more clearly establish defined and transparent criteria that will be used to select candidate technology for TCET review. This will help bring additional certainty for TCET pathway candidates until additional resources to further expand the pathway can be identified.

Thank you for the opportunity to provide these comments. Please contact Molly Peltzman, Associate Director of Health Policy, at mpeltzman@sts.org or Derek Brandt, Vice President of Government Relations at dbrandt@sts.org should you need additional information or clarification.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas E. MacGillivray". The signature is fluid and cursive, written in a professional style.

Thomas E. MacGillivray, MD
President