December 28, 2024

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: Extension of Information from Transcatheter Valve Therapy (TVT) Registry [CMS-10443]

Dear Administrator Brooks-LaSure,

On behalf of The Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC), we write to provide comments on CMS' intention to collect information using the TVT Registry for the development of a national coverage determination (NCD). The Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry™, established in 2012, collects and analyzes data on patients undergoing transcatheter valve interventions, including procedures such as transcatheter aortic valve replacement (TAVR), transcatheter mitral valve repair (TMVR) and emerging transcatheter tricuspid valve replacement and repair (TTVRr).

Our organizations appreciate the continued partnership with CMS to collect data on TVT technology using the STS/ACC TVT Registry™. The registry is a prime example of how the use of clinical data registries can capture real world evidence to inform clinical practice and regulatory decisions. By doing so, it ensures CMS can make informed decisions based on the best available clinical evidence. To that end, we strongly support CMS' utilization of the STS/ACC TVT Registry™ for purposes of Coverage with Evidence Development (CED) for TVT technology.

Over the past decade, the STS/ACC TVT Registry™ and Coordinated Registry Network has supported 23 regulatory decisions and ensured evidence-based evaluation of TVT technology. When TAVR was first approved under the NCD with CED in 2012, it was limited to high-risk patients that were too health-compromised to undergo open heart surgery for surgical aortic valve replacement (SAVR). Over time, intermediate and low risk populations have gained access to this once novel therapy based on the data collected through our registry. This method of evidence generation creates value for manufacturers and the broader device ecosystem with significant benefits to public health. Additionally, this model of data collection through the STS/ACC TVT Registry™ sets the standard for newer technologies like the recently FDA-approved devices for transcatheter tricuspid valve replacement and repair that are currently undergoing two national coverage analyses by CMS.

In the development of the STS/ACC TVT Registry™, we have implemented measures to ensure data collection balances administrative burden with the need for comprehensive data points to ensure useful analyzed datasets for varied stakeholders. For example, for the TAVR component of the STS/ACC TVT Registry™, we developed a minimum data set that contains the variables needed to meet quality metrics and risk modeling analysis. This way, sites are given the option to complete the minimum or full dataset, which includes more variables and requires more time, depending on their specific needs. Additionally, several health care systems are leveraging the data structure of the registry to enable mapping many of the TVT Registry data elements to their electronic health records which will ease the data abstraction effort and facilitate data submission.

Our organizations look forward to our continued collaboration with CMS in leveraging the STS/ACC TVT Registry™ to inform and optimize clinical outcomes. Please contact Molly Peltzman, Associate Director of Health Policy at STS, at mpeltzman@sts.org or Amanda Stirling, Regulatory Affairs Associate at ACC, at astirling@acc.org should you need additional information or clarification.

Sincerely,

Jennifer C. Romano, MD, MS
President
The Society of Thoracic Surgeons

Cathleen Biga, MSN, FACC
President
American College of Cardiology