Medtronic News

Medtronic to Provide Public Comment During CMS Committee Meeting on Volume Requirements for Transcatheter Aortic Valve Replacement (TAVR)

Company to Emphasize the Importance of Evidenced-Based Quality Outcomes and Appropriate Patient Access

DUBLIN and BALTIMORE - July 25, 2018 - Medtronic plc (NYSE:MDT), a global leader in heart valve therapies, will deliver public comment during the Centers for Medicare & Medicaid Services (CMS) Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) meeting on July 25, which will assess whether scientific evidence supports requiring hospitals and heart team members to meet pre-specified volume requirements for TAVR programs.

"While considering requirements for centers and physicians to deliver quality outcomes, patient access is equally important, and we believe that any coverage policy and patient access decisions need to be supported by high-quality empirical evidence," said Pieter Kappetein, M.D., vice president and chief medical officer of the Structural Heart business, which is part of the Cardiac and Vascular Group at Medtronic. "The evidence that we've seen to date does not show a correlation between volume and quality."

The MEDCAC panel will vote on nine questions regarding whether there is sufficient evidence supporting procedural volume requirements for operators and hospitals. The vote results will be made public following the meeting.

Medtronic will deliver a five-minute presentation in general support of the existing TAVR National Coverage Determination (NCD), reinforcing the position that the current coverage policy allows for appropriate patient access to TAVR therapy while achieving quality outcomes.

"We do not believe there is sufficient evidence to support significant modifications to the current operator and facility volume requirements in the TAVR NCD at this time," said Kappetein. "We will continue to collaborate with key stakeholders as the NCD process moves forward, and we are committed to delivering meaningful, evidence-based solutions across the care continuum that provide excellent outcomes for heart valve patients across the globe."

Medtronic is a leading innovator of heart valve therapies, including the first transcatheter pulmonic valve, the first self-expanding and recapturable transcatheter aortic valve, and the first transcatheter mitral valve replacement technology to be studied in a global pivotal trial.

Following the MEDCAC meeting, Medtronic will participate in the Open Comment period for the TAVR national coverage analysis (NCA) and will provide several recommendations to ensure patients will continue to have sufficient access to TAVR therapy.

In collaboration with leading clinicians, researchers, and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 86,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

-end-

Contacts:

Joey Lomicky
Public Relations
+1-763-526-2494

Ryan Weispfenning
Investor Relations
+1-763-505-4626

---

https://news.medtronic.com/2018-07-25-Medtronic-to-Provide-Public-Comment-During-CMS-Committee-Meeting-on-Volume-Requirements-for-Transcatheter-Aortic-Valve-Replacement-TAVR