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The Society of Thoracic Surgeons, the American College of Cardiology, the Heart Failure Society of America, and the American Association for Thoracic Surgery are submitting comments on the reconsideration of the national coverage decision (NCD) for artificial hearts and related devices.

The medical specialty societies representing the providers treating patients who require artificial hearts and related devices for lifesaving and life-sustaining support do not agree with the proposal to remove the requirement for coverage with evidence development (CED) for artificial hearts and related devices. We believe that data collection and continued participation in a national registry should be required for all such devices. Further, there are many clinical questions about artificial hearts that still need to be answered. Proposed clinical questions for continued CED include:

1. In what clinical scenarios is the total artificial heart appropriate to use rather than a left ventricular assist device or biventricular assist device support.
2. What are long-term risks inherent with TAH use?
3. Does the TAH have a safety and durability profile acceptable for long-term use; i.e., 2 years or greater?
4. Are patient-centered outcomes on the TAH acceptable and improved compared to patients with advanced heart failure or patients living with left ventricular assist device support?
5. Are results from pre-market clinical trials replicable in real word populations?

Thank you for the opportunity to provide comments. The medical specialty societies oppose the removal of a CED requirement for artificial hearts and related devices at this time. Should you have any questions, please contact Courtney Yohe Savage, Director of Government Relations for The Society of Thoracic Surgeons at 202-787-1222 or cyohe@sts.org.

Sincerely,

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