



September 11, 2020

Tamara Syrek-Jensen
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Dear Ms. Syrek-Jensen,

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 proposal to eliminate national coverage for artificial hearts and related devices.

We oppose eliminating national coverage for artificial hearts and related devices. It is the societies' experience that National Coverage Decisions are deployed when disparate coverage policies across contractors exist or are expected, when complex or novel or resource-intensive services are under consideration, or when concerns about overutilization/misutilization exist. Several of these considerations apply to artificial hearts, the most important of which is the potential to limit access to therapy due to coverage. Inconsistent and inaccurate coverage policy creates access limitations and disparities that impose significant administrative burden on providers and stress on seriously ill patients. Sometimes patients are referred to another state where coverage is more appropriate and allows a therapy the physician and patient agree is necessary. Local factors are not irrelevant, but the societies believe in and affirm the value of having a floor for coverage for artificial hearts.

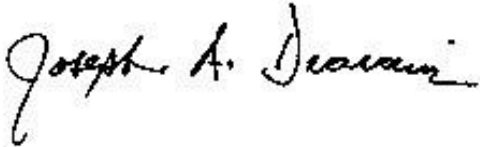
Significantly, current gaps in our understanding of the utility of treatment using artificial hearts and related devices could contribute to disparate local coverage decisions. Therefore, we reiterate our request to restore coverage with evidence development (CED) for artificial hearts. There are many 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?

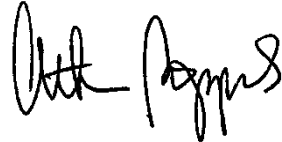
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Thank you for the opportunity to provide comments. Should you have any questions, please contact Courtney Yohe Savage, Director of Government Relations for The Society of Thoracic Surgeons at 202-787-1222 or cyohe@sts.org.

Sincerely,



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The Society of Thoracic Surgeons



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