

December 23, 2020

The Honorable Alex M. Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Secretary Azar and Administrator Verma,

The undersigned organizations are writing to urge CMS to release its final national coverage decision (NCD) memo for mitral valve Transcatheter Edge-to-Edge Repair (TEER), also referred to as Transcatheter Mitral Valve Repair (TMVR). The TEER procedure has shown promising outcomes for clinically appropriate patients and provides a minimally invasive treatment option for patients who are not candidates for surgical repair. The proposed decision memo (CAG-00438R) was released on June 30th. As mandated by law, the NCD should have been finalized prior to the end of September.ⁱ

The decision memo proposes to expand Medicare coverage and advance innovative treatment for mitral regurgitation (MR) for Medicare beneficiaries. This change would constitute a breakthrough by extending coverage of TEER for patients with functional MR, which is a disease of the left ventricle that leads to problems with the mitral valve and is often accompanied by heart failure. The standard of care for such patients is guideline-directed medical therapy (GDMT), not surgery. These patients are frequently too sick to tolerate surgery, let alone invasive open-heart surgery, which has not demonstrated a clinical benefit in such patients, making medical therapy alone (until the recent introduction of TEER) their only option. In ongoing clinical studies, combining TEER with GDMT lowers risk of death by one-third and heart-failure hospitalizations by half when compared to GDMT alone.ⁱⁱ For these Medicare patients, the continued wait for CMS to release of the TEER NCD does not represent an administrative delay. Instead, the significance of not having access to TEER has life-and-death consequences.

As a number of our organizations commented in a [July 30 letter](#), CMS needs to issue a final decision reflecting changes to its TEER coverage policy that would provide adequate access for Medicare patients with mitral valve disease, including: less restrictive procedural volume and site coverage requirements; transparent post-market data collection; and permit telehealth visits to satisfy examination requirements; among others.

We applaud CMS for the steps it has taken to advance innovation for Medicare patients, and we thank the agency for adopting recommendations from advocacy organizations representing patients and family caregivers in its draft TEER NCD. Now, it is time for CMS to take immediate action and finalize the coverage decision so that Medicare beneficiaries in need may access this life-saving treatment.

Sincerely,

Alliance for Aging Research
Association of Black Cardiologists
HealthyWomen
Heart Valve Voice US

National Hispanic Medical Association
National Minority Quality Forum
Men's Health Network
The Mended Hearts, Inc.

ⁱ [Social Security Act, Section 1862\(l\)\(3\)\(B\)](#). This section of the Act indicates that following release of a draft decision memo, CMS will provide a 30-day period for public comment, followed by a final decision “not later than 60 days after the conclusion of the 30-day comment period.”

ⁱⁱ Mack M. [COAPT: Three-Year Outcomes from a Randomized Trial of Transcatheter Mitral Valve Leaflet Approximation in Patients with Heart Failure and Secondary Mitral Regurgitation](#). Presented at TCT 2019.