HFSA
HEART FAILURE SOCIETY OF AMERICA
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July 30, 2020

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

RE: Proposed Decision Memorandum for Transcatheter Mitral Valve Repair (TMVR) (CAG-00438R)

Dear Ms. Syrek-Jensen:

On behalf of the Heart Failure Society of America (HFSA), I am writing to provide input on the Agency's proposed decision memorandum for national coverage of Transcatheter Mitral Valve Repair (TMVR). The vision of the Heart Failure Society of America is to significantly reduce the burden of heart failure. HFSA is a multidisciplinary organization working to improve and expand heart failure care through collaboration, education, research, innovation, and advocacy. We appreciate the opportunity to comment on this National Coverage Determination (NCD).

Coverage with Evidence Development (CED)

We believe that our patients benefit from thoughtful NCDs that are based in science and provide for the advancement of new technologies and therapies. Because of this, we are concerned with the Agency's change of course regarding coverage with evidence development (CED). We find CMS' proposal to eliminate data collection under CED for TMVR particularly problematic given the prospect this has for limiting patient access to treatment and reducing, rather than expanding, the amount of information available for clinical decision-making. We do not believe that eliminating data collection under CED is a move toward patient-centered care and are concerned about the Agency's proposal to eliminate it. For heart failure patients in particular, we are concerned about the negative impact that this decision will have on the infrastructure needed to follow long-term outcomes and request that the Agency reconsider its proposal.

In addition, HFSA opposes CMS' proposal to remove CED for transcatheter edge-to-edge repair (TEER) for both DMR and FMR. Heart failure patients may have functional MR and may be adversely impacted if TEER for both DMR and FMR is not covered. HF patients would lose access to a treatment modality by this proposal, [1] and we urge the Agency to reconsider.

[1] HFSA concurs with the statements made by AATS, ACC, STS, and SCAI, in their response to the proposed decision memorandum, "***Importantly, the two pivotal clinical trials for FMR with modest study populations that led to FDA approval offer divergent conclusions in terms of optimum patient selection and benefit for TEER, an area that could be very effectively answered through CED.*** *In fact, the remaining questions present after the results of these two randomized trials with discrepant results are precisely those that can be best answered and are prime examples of why CED was initiated by CMS. Furthermore, in the coming years, TEER will have substantial device iterations that can be assessed in terms of the long-term effectiveness utilizing CED coverage*."

Approach to Coverage for Functional Mitral Regurgitation (FMR) and Degenerative Mitral Regurgitation (DMR)

In addition to CMS' change of position on CED, the Agency proposes to bifurcate coverage approaches for TMVR whereby CMS would maintain national coverage for functional mitral regurgitation (FMR), but relegate degenerative mitral regurgitation (DMR) coverage to local coverage decisions by each individual Medicare Administrative Contractor, likely resulting in variable coverage approaches for TMVR for DMR across the country. HFSA does not believe that this best serves the interests of patients, which should be the key decision driver in developing these policies. It is difficult for us to provide additional input because CMS' provided rationale for this proposal does not align with current evidence. Not only are we concerned about this from the patient care perspective, but we stand with our partners at the American Association for Thoracic Surgery (AATS), the American College of Cardiology (ACC), the Society of Thoracic Surgeons (STS), and the Society for Cardiovascular Angiography and Interventions (SCAI) in recognizing that, clinically speaking, there are significant clinical challenges in differentiating DMR from FMR. A coverage policy premised on this differentiation could lead to delays in care and administrative complications that undermine the best care for patients. We believe that a coherent and rational coverage policy for both DMR and FMR must be developed at the national level to support the science behind their treatments and best serve the patients who are need of this care.

For these reasons, we request that CMS reconsider its approach to coverage for these procedures. If we can be of any assistance, please do not hesitate to contact us at sramthun@hfsa.org.

Sincerely,

Biykem Bozkurt, MD, PhD, FHFSA
President
The Heart Failure Society of America