



July 30, 2020

**SUBMITTED ELECTRONICALLY**

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

RE: National Coverage Analysis (NCA) for Transcatheter Mitral Valve Repair (TMVR)  
(CAG-00438R)

Dear Ms. Syrek Jensen,

Edwards Lifesciences (“Edwards”) thanks CMS for the opportunity to comment on the National Coverage Analysis (NCA) for Transcatheter Mitral Valve Repair (TMVR) (CAG-00438R). This cover letter serves as a summary of our attached detailed comments, which review the current scientific data and our recommendations based on those data.

Edwards appreciates CMS’ commitment to ensuring patient access to new medical therapies through the current policy review. We are encouraged by elements within the draft NCD that will enable mitral valve disease patients to have improved, prompt access to therapy options.

As background, despite the excess mortality associated with mitral regurgitation (MR), a significant number of these patients are not referred for surgery, as they may be considered inoperable or at high surgical risk because of age or comorbidities.<sup>1-4</sup> TMVR therapy addresses an unmet patient need and has saved lives and dramatically improved the quality of life of patients over the duration of the existing NCD. In addition, as this field continues to emerge, and new evidence is generated, new therapies will be incorporated into clinical practice.

Based on the additional insights gained through study and therapy development since the publication of the NCD in 2014, we believe the policy should be updated to ensure patients have timely access and high-quality outcomes through comprehensive care under the guidance of a Heart Team, with particular consideration of the following:

**We believe CMS can use Coverage with Evidence Development (CED), requiring reporting of outcomes in a streamlined registry for a defined period of time, to collect real-world data that ensures high-quality care and enables patient access to new lifesaving therapies with labeled indications.** We recommend continuing requirements for participation in a registry, while significantly reducing the data requirements to approximately 50 fields of the most critical information and limiting the duration of the participation to three years. We believe this will ensure high-quality procedures, allow for coverage to label for all TMVR devices and modernize the site requirements to reflect consistency with transcatheter aortic valve replacement (TAVR) site requirements.

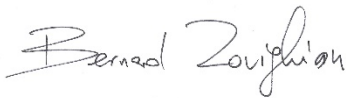
**We recommend returning Degenerative Mitral Regurgitation (DMR) coverage from Medicare Administrative Contractor (MAC) discretion back to the NCD to preserve timely patient access to current and future therapies and to allow for continued data collection to support quality patient outcomes.** Deferring future coverage determinations to MACs could negatively impact patient access if some MACs choose to implement restrictive coverage policies.

Other areas for consideration include the following, which are detailed in the full comment letter that is attached:

- **Allow in-person, face-to-face provisions to be satisfied with telehealth visits.** During the COVID-19 global public health emergency, CMS preserved continuity of care for structural heart disease patients by allowing them to receive telehealth exams by the Heart Team cardiac surgeon and interventional cardiologist, rather than face-to-face exams. While intended as a temporary measure, we recommend incorporating permanently this provision to support aspects of eligibility evaluation.
- **Removal of surgeon sign-off for eligibility.** When the initial TMVR NCD was implemented, the policy was limited to the treatment of significant symptomatic DMR, a disease for which there exists a surgical treatment. This same requirement, however, is not applicable to functional mitral regurgitation (FMR) patients, where determination of surgical risk is not applicable. We believe it would be more appropriate to replace the surgeon sign-off for eligibility with a heart failure specialist to support the determination of appropriateness for transcatheter mitral therapy.
- **Eliminate exclusion criteria.** In the proposed decision memo, CMS provides seven different conditions for which treatment of FMR with transcatheter mitral leaflet approximation is not covered. Continuing the CED registry requirement would allow for timely and ongoing evaluation of the benefits of transcatheter mitral therapy in these sub-populations and ensure access to therapies that FDA has determined are safe and effective.
- **Revise the title to reflect transcatheter mitral leaflet approximation (TMLA).** It appears CMS intends to define the therapies covered by the policy to be inclusive of catheter-based therapies that approximate the edges of the anterior and posterior mitral valve leaflets at the site of regurgitation. Therefore, we recommend clarifying this intention by revising to a title that more accurately reflects all leaflet approximation therapies.

Edwards thanks CMS for its consideration of our attached TMVR clinical evidence summary and recommendations for the NCD reconsideration. We look forward to working closely with CMS throughout the NCA process and to providing any additional information that CMS may require. For further information, please contact me at 949-250-2500, or at [Bernard\\_Zovighian@edwards.com](mailto:Bernard_Zovighian@edwards.com).

Sincerely,



Bernard Zovighian  
Corporate Vice President, Transcatheter Mitral and Tricuspid Therapies  
Edwards Lifesciences

---

<sup>1</sup> McCullough PA, et al. The healthcare burden of disease progression in Medicare patients with functional mitral regurgitation. *J Med Econ*. 2019 Sep; 22(9):909-916.

<sup>2</sup> Nishimura RA, Otto CM, Bonow RO, et al. 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2017;135(25):e1159-e1195.

<sup>3</sup> Baumgartner H, Falk V, Bax JJ, et al. 2017 ESC/EACTS Guidelines for the management of valvular heart disease: The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). *Eur Heart J*. 2017.

<sup>4</sup> Carabello B. The current therapy for mitral regurgitation. *J Am Coll Cardiol*. 2008;52(5):319-326.