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April 29, 2019

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

RE: Request for Reconsideration of the Transcatheter Mitral Valve Repair (TMVR)  
National Coverage Determination (NCD) 20.33

Dear Ms. Syrek-Jensen:

The Society of Thoracic Surgeons (STS), the American College of Cardiology (ACC), the American Association for Thoracic Surgery (AATS), and the Society for Cardiovascular Angiography & Interventions (SCAI) are submitting a formal request for CMS reconsideration of the current transcatheter mitral valve repair (TMVR) national coverage decision (NCD). This request is driven by new scientific evidence showing that TMVR is beneficial to patients with secondary or functional mitral regurgitation (FMR) and recent approval of a new patient indication by the Food & Drug Administration (FDA). Patients with FMR that would potentially benefit from TMVR with one specific device are not covered under the existing NCD, which is limited to degenerative mitral regurgitation (DMR). Our request summarizes and cites the new evidence, highlights the necessity of continued data collection for this evolving technology, and reiterates that TMVR patients should be cared for by a heart team.

### **Description of Technology**

TMVR procedures utilize emerging technologies to treat symptomatic patients with moderate to severe or severe mitral regurgitation (MR) based on American Society of Echocardiography guidelines. Patients that currently qualify for this intervention are either non-operative or high-risk operative candidates based on the STS Risk Score, and a consensus from the heart team which includes an experienced mitral valve surgeon and an interventional cardiologist experienced in mitral valve disease who agree on the appropriate use of this technology.

TMVR procedures are performed utilizing catheter-based technology and involve approximating the leaflets of the mitral valve with a clip device. Currently, Abbott's

MitraClip® is the only device with FDA approval to provide TMVR. Investigational devices include another clip device and those that reduce the size of the mitral valve annulus or implant new mitral valve supporting structures (chordal implants). Transcatheter mitral valve replacement devices are currently in early feasibility and pivotal trials in the US. Mitral clipping and most approaches to annular reduction are done through a transvenous approach in which the device reaches the left-sided mitral valve by crossing through the inter-atrial septum while the chordal implants are done via a limited left anterior thoracotomy and a transapical approach. Transcatheter mitral valve replacement options include transvenous (transseptal) and transapical approaches.

Medicare beneficiaries receive TMVR under the Part A inpatient hospital services and Part B physician services benefit categories, and that would continue to be the case.

### **Scientific Evidence**

A recent randomized trial in patients with secondary mitral regurgitation, the COAPT Trial<sup>1</sup> compared TMVR with the MitraClip device plus optimal guideline directed medical therapy (GDMT) to GDMT alone. The primary endpoint of the trial, heart failure hospitalizations at two years was highly significant for the treatment arm with the number of patients needed to be treated (NNT) to prevent a heart failure hospitalization in 24 months being 3.1. There was also a mortality benefit with a 38% reduction in all cause death at two years with the NNT of 5.9 to prevent a death. All prespecified and powered secondary endpoints favored TMVR over medical therapy alone.

A similar trial with different inclusion criteria, Mitra-Fr<sup>2</sup>, also examined outcomes of TMVR and medical therapy versus medical therapy alone in patients with secondary MR. However, the results were neutral and inconclusive, in regard to the additional benefit of TMVR over medical therapy alone.

There were some significant differences in trial inclusion/exclusion criteria and trial conduct that may explain the discrepancy. Patients in Mitra-FR had more significant left ventricular remodeling as a result of long-standing MR and thus were less likely to benefit from TMVR. COAPT patients were carefully screened to make sure they had a better chance of clinical response to MitraClip. Patients in the Mitra-FR trial would not be considered candidates at well-run valve centers adhering to the inclusion criteria of COAPT when selecting patients for MitraClip. Investigators and practitioners in the field feel that there is robust evidence that correction of secondary MR with this device is beneficial to patients and should be accessible for patients who meet the criteria of the COAPT trial.

These two trials also underscore the role for guideline directed medical therapy.

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<sup>1</sup> Stone, GW. Transcatheter Mitral-Valve Repair in Patients with Heart Failure. N Engl. J Med 2018; 379:2307-2318.

<sup>2</sup> Obadia, JF. Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation. N Engl J Med 2018; 379:2297-2306.

## **Description of Service**

### *Percutaneous transcatheter mitral valve repair using a leaflet plication*

After general anesthesia is induced, the patient is intubated. Access sites are prepped. Transesophageal echocardiography probe is inserted and positioned by a separate physician who is not the surgeon or interventional cardiologist. Venous access is obtained for right heart catheterization and evaluation of pulmonary pressures and transseptal puncture. Arterial access is also gained for pressure measurement and angiography. Baseline right heart catheterization is performed to assess intra-cardiac hemodynamics, including cardiac output, pulmonary arterial pressure and pulmonary capillary wedge pressure. A wire is advanced from the right femoral vein to the right atrium for placement of the transseptal sheath & needle. The transseptal sheath and needle are now inserted over the wire and using echocardiographic guidance entry into the right atrium is confirmed. Transseptal puncture to gain access to the left atrium is performed with echo verification of correct puncture location. The patient is heparinized and the Activated Clotting Time (ACT) is checked. The activated clotting time [ACT] level should be > 250 seconds and continuously checked every 30 minutes. Heparin is re-administered as necessary to assure the patient is therapeutically anticoagulated. At this point a stiff guide wire is placed through the transseptal sheath into the left atrium and then pulmonary vein. The mitral valve repair device is prepared on the back table.

The femoral vein access site is progressively dilated with a series of dilators. The guide catheter is advanced over the wire into the left atrium, the wire is removed, and the guide catheter is de-aired. The mitral valve repair device and delivery system are advanced through the guide to the left atrium. Extreme care is required to avoid air embolization to the left side of the heart. The prosthesis is then positioned above the mitral valve using echocardiographic and fluoroscopic guidance. Multiple echocardiographic and fluoroscopic views are utilized to guide a complex series of maneuvers to position the prosthesis at the proper position within the mitral valve, with careful avoidance of other structures. The device is then deployed, grasping and coapting the anterior and posterior mitral leaflets thereby reducing mitral regurgitation. Multiple attempts at properly grasping the two leaflets are often required. Echocardiographic and fluoroscopic imaging is then used to ensure proper device positioning and leaflet insertion into the device, and adequate reduction in the mitral regurgitation. If the evaluation is favorable the device is released in a series of steps. After final release the patient is again evaluated by angiographic, hemodynamic and echocardiographic criteria for suitability of the mitral valve repair and to ensure no complications. If there is no need for an additional device, the delivery system is withdrawn and removed from the body with closure of the venous access.

Anesthesia is reversed, and the patient is extubated as appropriate. Hypertension, hypotension, bleeding and oxygen desaturation are potential complications and are treated accordingly with medications and/or oxygen as needed during the procedure.

### *Transcatheter mitral valve repair using annulus reduction or chordal implant*

A number of direct and indirect annuloplasty devices and chordal implant devices are in varying degrees of evaluation but not yet FDA approved. The current coverage approach that includes FDA-approved devices for FDA-approved indications would be an appropriate way to address them if that changes.

#### **Status of FDA Regulatory Review**

The Food & Drug Administration approved a new indication for the MitraClip on March 14 based on these recent trials. The new indication is for “treatment of patients with normal mitral valves who develop heart failure symptoms and moderate-to-severe or severe mitral regurgitation because of diminished left heart function (commonly known as secondary or functional mitral regurgitation) despite being treated with optimal medical therapy. Optimal medical therapy includes combinations of different heart failure medications along with, in certain patients, cardiac resynchronization therapy and implantation of cardioverter defibrillators.” The societies believe this change in indications warrants revision of the TMVR NCD. As currently written, TMVR for patients with FMR would not be covered by the NCD.

#### **Target Medicare Population & Medical Indications**

Since 2014, TMVR procedures have been limited to Medicare beneficiaries who suffer significant symptomatic DMR. Based on the above evidence, the TMVR NCD should be revised to include FMR consistent with FDA-approved indications.

The four societies are working to review and update the current expert consensus document, the “SCAI/AATS/ACC/STS Operator & Institutional Requirements for Transcatheter Valve Repair and Replacement, Part II—Mitral Valve.” A revised TMVR NCD should still require that TMVR patients receive care from a multidisciplinary heart team and data on TMVR procedures be collected in a prospective, national, audited registry, similar to the conditions in the current NCD. Since FMR is a condition causing congestive heart failure, at least one team member should be focused on the clinical and medical aspects of the patient’s heart failure. The success of the COAPT Trial was in large part due to optimization and maintenance of GDMT, appropriate patient selection, and post procedure management by this team member.

Data collection under coverage with evidence development (CED) remains critical in order to track the outcomes questions from the current NCD—all-cause mortality, stroke, repeat mitral valve surgery or other mitral procedures, worsening MR, transient ischemic events, major vascular events, renal complications, functional capacity, Quality of Life, outcomes and adverse events outside the pivotal clinical studies, outcomes and events in subpopulations outside the pivotal clinical studies, long term ( $\geq 5$ -year) durability of the device, long-term ( $\geq 5$ -year) outcomes and adverse events, and patient demographics outside the pivotal studies.

## Language for NCD Revision

The societies believe that a narrow approach to revising coverage for TMVR is appropriate, though some recognition of differences between degenerative and functional MR are necessary.

- First, we recommend deleting the word “degenerative” from Section A. of the NCD to allow for treatment of functional MR.
- Second, we recommend adding the phrase, “For degenerative MR,” at the beginning of Section A. 2.
- Third, to distinguish care pathways between degenerative MR and functional MR, we recommend a new section A. 3. below that indicate that, “For functional MR, a team member with experience in the management of heart failure has examined the patient face-to-face and documented the rationale for their clinical judgement. That specialist should document that the patient is on maximal guideline directed medical therapy (GDMT), has received resynchronization therapy if appropriate and is likely to benefit from intervention on the MR.”

This also allows for different indications for functional MR in the latest FDA approval order. Those changes should allow covered indications to track with FDA indications. Modest adjustments to the supplementary conditions for operator and institutional standards will be necessary in order to align with the pending update of the SCAI/AATS/ACC/STS Operator & Institutional Requirements for Transcatheter Valve Repair and Replacement, Part II—Mitral Valve<sup>3</sup> expert consensus document and we are working to complete that document as quickly as possible for it to be useful in writing the draft NCD.

## Future Considerations

Studies are underway to explore a role for transcatheter mitral valve replacement as a therapy for mitral regurgitation. The current understanding from [clinicaltrials.gov](http://clinicaltrials.gov) is that primary completion dates are more than two years away with study completion dates as much as four years after that. Given the lack of data available for TMV replacement, this request is limited to TMV repair. However, confusion about these two terms is already causing difficulties. At some point it may be necessary to consider these therapies separately or together as part of a broader transcatheter mitral valve *therapy* NCD. In the interim, it will be useful to begin distinguishing TMV *repair* from TMV *replacement*. A revised NCD would be a good place to start using that clarifying terminology.

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<sup>3</sup> Tommaso, CL. SCAI/AATS/ACC/STS Operator and Institutional Requirements for Transcatheter Valve Repair and Replacement. Part II. Mitral Valve. J Am Coll Cardiol 2014; 64:1515-1516.

Thank you for your consideration of this request for reconsideration. The societies look forward to working with you and your team during the reconsideration process and are available to provide additional information or answer questions along the way.

Sincerely,

*David Cox, MD*

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