June 13, 2014

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

RE: Proposed Decision Memo for Transcatheter Mitral Valve (TMV) Procedures (CAG-00438N)

Dear Ms. Syrek Jensen:

Overview

The Society of Thoracic Surgeons (STS), the American College of Cardiology (ACC), and the Society for Cardiovascular Angiography and Interventions (SCAI), appreciate this opportunity to comment on the proposed decision memo. We support CMS’ decision to approach transcatheter mitral valve repair (TMVR) as a technology that warrants further study and agree that utilizing coverage with evidence development (CED) is appropriate. Further, we agree that TMVR should be available for use by expert heart teams in valve centers of excellence for the treatment of select, appropriate patients who can benefit optimally from its use. We support the general direction of the conditions of coverage outlined in the attached proposed decision memorandum. (Attachment 1) However, we are concerned the following requirement may be unnecessarily restrictive.

4. The heart team’s interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TMVR.

We also note other specific edits we believe would improve the coverage decision related to specific staffing requirements and clinical trials.

Guiding Principles

In these comments, the societies are guided by the following principles:

• Care of TMVR patients should be guided by the multidisciplinary heart team.
• The physicians who care for these patients are capable of determining which patients will need joint intraoperative care and should be allowed to do so based upon the clinical needs of the patient.
• Coverage should benefit patients now with the technology that currently exists while remaining flexible enough to accommodate any future developments.
• Patient access should not be delayed by a requirement for joint intraoperative care when the procedure can be successfully completed by one operator, as determined by the heart team.
• We fear hospitals may be less inclined to offer repair through use of the Mitral Valve Clip (or comparable device) if a federal mandate for joint intraoperative care is universally imposed and increases costs to an unsustainable level.

Recommendations Summary

Clinical trials and practice indicate that TMVR using current technology is nearly universally performed by a single physician. We make the following recommendations for changes to the proposed decision memorandum:

1. We recommend CMS revise condition four which would establish a universal requirement for joint intraoperative participation.
2. We recommend CMS explicitly provide coverage and payment for both physicians in cases where a patient’s clinical condition might warrant joint intraoperative participation by an interventional cardiologist and cardiac surgeon.
3. We recommend CMS cover TMVR for uses not expressly listed as an FDA approved indication when performed within an FDA-approved clinical study.
4. We specify revisions to the composition of the heart team that are more realistic for clinical practice.
5. We request CMS work with ACC and relevant societies to update decisions as required by the introduction of new technology.

Supporting Information

Coverage and Payment Should Provide the Option for Joint Intraoperative Participation
Current and future technologies for TMVR may warrant joint intra-operative participation by both a cardiologist and surgeon. We agree coverage and payment should reflect the work of both physicians in situations where a patient’s clinical condition might require joint intraoperative participation. **We recommend CMS assign relevant TMVR codes co-surgery indicator 2 in the physician fee schedule that allows cosurgery “if two specialty requirements are met.”**

Clinical Trials on the Mitral Clip Do Not Support a Mandate for Joint Intraoperative Participation
The only device currently approved by FDA for TMVR, Abbott’s MitraClip, proceeded through clinical trials and FDA-approval without any indication that joint intraoperative participation is required for procedural success. FDA’s post-approval study does not require two operators. Lastly, a dual-operator requirement was not part of trial protocols or discussed in journal articles for the COAPT, RESHASPE-HF, EVEREST II, EVEREST HRR, or REALISM trials. It is not included as part of FDA’s labeling, indications, or Abbott’s instructions for use.
Additionally, the recently published competency document indicates the importance of collaboration by the heart team and the possibility that the expertise of two physicians could be required. It also explicitly states “the procedure is commonly performed by a single physician.”

_CPT and RUC_
Throughout the CPT and RUC process it was made clear that TMVR, performed with the device currently approved by the FDA, is typically performed by a single operator. While that does not prohibit the use of an appropriate modifier for two operators, surgical team, assistant surgeon, or minimum assistant surgeon, it speaks to the fact that at no point during the process was the prospect of a dual-operator requirement supported by evidence or involved stakeholders.

_We recommend revision of the requirement for joint participation in the intra-operative technical aspects of transcatheter deployment of mitral valve clips by the heart team’s interventional cardiologist and cardiac surgeon._ We propose CMS revise the fourth condition of coverage to confirm that coverage expressly includes, but does not require, joint participation in the intra-operative technical aspects of TMVR when appropriately provided and documented. We also propose to revise the second condition of coverage to provide that both physicians will agree and document whether a patient would be expected to require joint intraoperative participation. We are happy to work with CMS to explore additional viable solutions to this problem. An attempt to execute the suggested revision is presented in redline below.

2. Both a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease have independently examined the patient face-to-face and evaluated the patient’s suitability for mitral valve surgery and determination of prohibitive risk; and both physicians have documented the rationale for their clinical judgment and the rationale is available to the heart team. This documentation indicates that both physicians agree joint participation is or is not anticipated for the service.

... 

4. The heart team’s interventional cardiologist(s) and cardiac surgeon(s) must may jointly participate in the intra-operative technical aspects of TMVR. _CMS covers services designated by two operators or assistant operator or surgical team modifiers when appropriately provided and documented._

These recommendations extend to condition number one in the clinical trial coverage section.

_Heart Team Composition_
Some of the specific requirements are misaligned with the way cardiac care is provided. For example, the requirement that the hospital have congenital heart disease specialists and surgeons at the institution is very restrictive. If a hospital is near a pediatric hospital, for example, that is where the expertise resides for congenital heart surgeons and that is the facility to which such patients are referred. It is unnecessary to demand that the adult hospital have such congenital specialists and surgeons on staff. A TMVR procedure would almost never require such expertise. _We recommend the following edits to the staff requirements in item f.4._

Additional members of the heart team needed for optimal, individualized patient care, including, when needed, echocardiographers, other cardiac imaging specialists, heart valve and
heart failure specialists, electrophysiologists, cardiac anesthesiologists, intensivists, intensive care and imaging departments, nurses, physician assistants, congenital heart disease specialists and surgeons, nurse practitioners, data/research coordinators and a dedicated administrator

Coverage in a Clinical Trial
We support CMS’ proposal to cover services for non-FDA-approved indications in clinical trials to ensure TMVR technology evolves in a safe and effective manner. However, we strongly urge CMS to reconsider its proposal to limit research coverage to randomized clinical trials which will unnecessarily hamper research into off-label uses in the U.S.

Specifically, a requirement for randomized clinical trials would limit exactly the sort of observational, registry studies CMS is encouraging through the proposed CED. We recommend the following language: “TMVR is covered for uses that are not expressly listed as an FDA approved indication when performed within an FDA-approved randomized clinical trial clinical study…”

Thank you for your careful consideration of these comments and your continued work on this complex issue. Please contact James Vavricek, ACC Associate Director of Medicare Payment & Coverage at jvavricek@acc.org, Courtney Yohe, STS Director of Government Relations at cyohe@sts.org, or Dawn Hopkins, SCAI Director of Reimbursement & Regulatory Affairs at dhopkins@scai.org you have questions or need additional information.

Sincerely,

Patrick T. O’Gara, MD, FACC
ACC President

David A. Fullerton, MD
STS President

Charles E. Chambers, MD, FSCAI
SCAI President

Attachment
cc: Kathy Bryant, Director of Practitioner Services
Attachment 1: CMS’ Proposed Conditions of Coverage

The Centers for Medicare & Medicaid Services (CMS) proposes to cover transcatheter mitral valve repair (TMVR) under Coverage with Evidence Development (CED) with the following conditions:

A. TMVR is covered for the treatment of significant symptomatic mitral regurgitation when furnished according to an FDA approved indication and when all of the following conditions are met.

1. The procedure is furnished with a complete transcatheter mitral valve repair system that has received FDA premarket approval (PMA) for that system’s FDA approved indication.

2. Both a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease have independently examined the patient face-to-face and evaluated the patient’s suitability for mitral valve surgery and determination of prohibitive risk; and both physicians have documented the rationale for their clinical judgment and the rationale is available to the heart team.

3. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care.

TMVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:

a. On-site heart valve surgery program,

b. Cardiac catheterization lab or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy offering catheterization laboratory-quality imaging,

c. Non-invasive imaging including expertise in transthoracic and transesophageal echocardiography,

d. Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications,

e. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures,

f. Appropriate volume requirements per the applicable qualifications below. Outlined below are qualification requirements for hospital surgical programs wishing to perform TMVR procedures. The hospital surgical program must have the following:

a. ≥ 25 total mitral valve procedures in the previous year of which at least 10 must be mitral valve repairs;

b. ≥1000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year;

c. Interventionalist with: ≥ 50 structural procedures per year including atrial septal defects (ASD) and patent foramen ovale (PFO) and trans-septal punctures; and

d. Additional members of the heart team including echocardiographers, other imaging specialists, heart valve and heart failure specialists, electrophysiologists, cardiac anesthesiologists, intensive care and cardiac imaging departments, congenital heart disease...
specialists and surgeons, nurse practitioners, data/research coordinators and a dedicated administrator; and device-specific training as required by the manufacturer.

4. The heart team’s interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TMVR.

5. The heart team and hospital are participating in a prospective, national, audited registry that: 1) consecutively enrolls TMVR patients; 2) accepts all manufactured devices; 3) follows the patient for at least one year; and 4) complies with relevant regulations relating to protecting human research subjects, including 45 CFR Part 46 and 21 CFR Parts 50 & 56. The following outcomes must be tracked by the registry; and the registry must be designed to permit identification and analysis of patient, practitioner and facility level variables that predict each of these outcomes:

i. Quality of Life (QoL);
ii. Functional capacity
iii. Stroke;
iv. All-cause mortality;
v. Transient ischemic events (TIAs);
vi. Major vascular events;
vii. Renal complications;
viii. Repeat mitral valve surgery or other mitral procedures;
ix. Worsening mitral regurgitation.

The registry should collect all data necessary and have a written executable analysis plan in place to address the following questions (to appropriately address some questions, Medicare claims or other outside data may be necessary):

- When performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?
- How do outcomes and adverse events in subpopulations compare to patients in the pivotal clinical studies?
- What is the long term (≥ 5 year) durability of the device?
- What are the long term (≥ 5 year) outcomes and adverse events?
- How do the demographics of registry patients compare to the pivotal studies?

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.