June 13, 2014

Tamara Syrek Jensen, JD
Acting Director, Coverage & Analysis Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Mailstop S3-02-01
7500 Security Blvd
Baltimore MD 21244

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

Dear Ms. Syrek Jensen:

The Advanced Medical Technology Association is pleased to offer the following comments on the Centers for Medicare & Medicaid Services’ (CMS) Proposed Coverage Decision Memorandum for Transcatheter Mitral Valve Repair (TMVR).1 Our comments below relate to (1) the requirement for randomized clinical trials in studies for unlabeled uses of TMVR, and (2) the proposed operator and institutional requirements.

AdvaMed’s member companies produce the life-saving and life-enhancing medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed supports the use of sound evidence to inform medical practice. In general, we view Coverage with Evidence Development (CED) as a means to generate additional evidence in cases where the available evidence regarding a promising medical technology or procedure is not sufficient to support national coverage. In such circumstances, coverage that is contingent on the development of additional evidence can enable beneficiary access to state-of-the-art medical treatments, particularly when the alternative would be non-coverage.

In the proposed decision memorandum, CMS proposes to cover TMVR under Coverage with Evidence Development (CED) when certain conditions are met. The proposed coverage decision

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is similar in structure to CMS’ coverage determination for Transcatheter Aortic Valve Replacement (TAVR) in 2012. We appreciate CMS thoughtful approach and application of learning from the TAVR NCD experience, which we understand contributed to certain elements of the proposed TMVR draft NCD. In particular, the proposed determination provides coverage when specific conditions are met, including:

- Procedure uses TMVR system that is FDA-approved (PMA) for that system’s FDA-approved indication and other conditions:
- Two physicians have examined the patient and documented the need (cardiac surgeon and cardiologist),
- Patient is under the care of a multi-disciplinary heart team,
- Hospital meets certain conditions, and
- Hospital and heart team participate in a national registry.

Further, CMS proposes to cover TMVR for uses that are not expressly listed as an FDA approved indication when it is performed within an FDA-approved randomized clinical trial (RCT) that fulfills certain requirements.

**RCT and FDA Approval Requirements**

Our primary concern relates to CMS’ proposal that coverage, in the case of an unlabeled use of TMVR, be permitted only in a randomized clinical trial. AdvaMed previously has commented that CED allows CMS to provide coverage within the context of studies that conform to standards spelled out in Medicare’s Clinical Trial Policy; and research meeting these standards can include a range of studies, from randomized clinical trials to observational research. CMS has relied on a range of research approaches in its various applications of CED.

For the purpose of FDA approval, the trial design should be under the purview of the FDA; and therefore, CMS need not prescribe a particular trial design or methodological approach.

In addition we are concerned that only FDA-approved trials would be considered for coverage. This requirement would exclude coverage for future physician-sponsored or society-sponsored studies that could further inform which patient groups experience the greatest benefit from TMVR.

**Recommendation**

We recommend removing the reference to “FDA-approved randomized” trials, and revising the language in Section B to state that “TMVR is covered for uses that are not expressly listed as an FDA approved indication when performed within a clinical trial that fulfills all of the following…”.

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This language is consistent with the language that was included in the NCD for Transcatheter Aortic Valve Replacement (TAVR) in 2012.³

**Proposed Operator and Institutional Requirements**

We agree that operator and facility criteria are important and need definition, and we appreciate the complexity of the procedure and the importance of maximizing a beneficiary’s chance for improved health outcomes. However, we are concerned about CMS proposal to require the heart team’s interventional cardiologist(s) and cardiac surgeon(s) to “jointly participate in the intraoperative technical aspects of TMVR.” We believe this proposed requirement is inconsistent with guidelines that were recently issued by a group of four medical societies. The consensus paper, entitled "Operator & Institutional Requirements for Transcatheter Valve Repair and Replacement, Part II – Mitral Valve," was developed jointly by the Society for Cardiovascular Angiography and Interventions (SCAI), the American Association for Thoracic Surgery (AATS), the American College of Cardiology (ACC) and The Society of Thoracic Surgeons (STS), and it specifically addresses this issue.

The joint societies’ recommendations state that the MitraClip procedure can be performed as a single physician procedure and in other cases with two operators (which may include either two interventional cardiologists, or an interventionalist and a cardiothoracic surgeon). The guideline indicates that the surgeon may provide direct intra-procedural support in some cases, or may act as the operator in the intervention. The recommendations do not require a co-surgeon for all TMVR procedures but rather cite it as a possible scenario for promoting the heart team approach.

CMS’ proposed operator and facility requirements are generally aligned with the joint societies’ recommendations. Additionally, the proposed NCD emphasizes the importance of the multidisciplinary heart team in the effective management of TMVR patients from the pre-procedure patient selection, intra-procedure management, through post-procedure management and discharge. However, we believe CMS’ proposal to require that “the heart team’s interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intraoperative technical aspects of TMVR” is inconsistent with the societies’ recommendations.

**Recommendation**

We therefore request that the proposed requirement for dual operator participation in the intra-operative elements of the TMVR procedure, for cases involving FDA approved and non-FDA approved indications, be deleted from the NCD.

AdvaMed greatly appreciates the opportunity to comment on these issues, which we believe to be relevant not only within the context of the TMVR coverage decision, but can have broader implications with respect to future CMS coverage determinations.

³ National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR), Medicare National Coverage Determinations (NCD) Manual, Publication 100-3, Section 20.32 (effective 5/1/2012).

If you have questions regarding these comments or if you require additional information, please contact Chandra Branham, JD, Vice President, Payment and Health Care Delivery Policy, at (202) 434-7219 or cbranham@AdvaMed.org.

Sincerely,

Donald May  
Executive Vice President  
Payment and Health Care Delivery Policy