



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:

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 and Interventions (SCAI) appreciate this opportunity to submit comments on the proposed decision memorandum and national coverage determination (NCD) for TMVR. The societies recognize the significant time and effort that went into producing the memorandum, including evaluating the recent evidence and listening to feedback from the clinical community and a variety of stakeholders.

The societies recognize the addition of indications for functional mitral regurgitation (FMR) following approval of this new patient indication by the Food & Drug Administration (FDA) as an important advancement for patient care. The inclusion of rigorous facility and operator standards, consistent with the *2019 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Mitral Valve Intervention*,¹ will bolster the likelihood of high-quality care.

However, the societies are very concerned about proposals to eliminate data collection under coverage with evidence development (CED) and to bifurcate coverage of TMVR, with FMR addressed in this NCD while degenerative mitral regurgitation (DMR) is pushed to local coverage under Medicare Administrative Contractors' discretion. These actions do not appear to be congruent with the current evidence and CMS precedent. The societies fear that these actions may place certain FMR patients at risk of suboptimal use as significant clinical evidence gaps still exist and that knowledge of the ideal patient population to benefit from treatment is yet to be clearly defined.

¹ Bonow, et al. J Am Coll Cardiol. 2020 Jul, 76 (1) 96-117.

Coverage with Evidence Development

The societies and many stakeholders are disappointed with the proposed NCD that has dropped evidence collection under CED for transcatheter edge-to-edge repair (TEER) for both DMR and FMR. **The decision to eliminate CED for TEER in the proposed NCD has substantial, negative ramifications for the management and safety of patients with significant symptomatic MR, whether degenerative or functional, and the societies strongly urge CMS to reconsider this proposal.** Importantly, data collection under CED is not linked to volume standards, which are addressed separately in these comments.

CMS indicates in the memo that it believes the existing evidence base developed under the current CED policy and other peer-reviewed publications has addressed initial concerns about both the generalizability of clinical trial results in Medicare beneficiaries treated in real-world facilities and the durability of degenerative MR improvements over longer time periods. The societies appreciate that more evidence exists now than when the initial NCD was finalized in 2014 but believe important information to ensure quality and improve care should still be collected and monitored through continued CED since a minority of patients with DMR, roughly 10,000 per year, are now treated with TEER.

Impact on FDA Device Approval and Monitoring

Since implemented in 2004, CMS's visionary policy on CED has allowed more rapid access for Medicare beneficiaries to new interventions, improved post-market evidence development, provided important new evidence for care decisions, and has led to clearer understanding of the risks and benefits of cardiovascular therapies for patients, providers, and payers. During the past decade, the STS/ACC Transcatheter Valve Therapy (TVT) Registry and Coordinated Registry Network supported 23 regulatory decisions and ensured evidence-based evaluation of TVT technology. This method of evidence generation creates value for manufacturers and the broader device ecosystem with significant benefits to the public health.²

CED offers the opportunity to assess uncertainty regarding long-term outcomes. It creates opportunities to fill post-market evidence gaps and better define patient benefit and risk balance with the development of validated markers of clinical outcome benefits that can be tracked in a post-market setting. Without CED to bolster post-market surveillance and studies, the societies' understanding is that FDA would need to alter, and likely slow, their approach to device approval requiring more robust pre-market clinical studies.

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

² Pappas, et al. *BMJ Surg Interv Health Technologies*. 2019, 1:e000003.

years, TEER will have substantial device iterations that can be assessed in terms of the long-term effectiveness utilizing CED coverage.

CED is an essential vehicle to accelerate beneficiaries' access to improved TEER therapy for both FMR and DMR that is reasonable and necessary while developing better evidence to inform care decisions. CED is particularly important, considering the relatively still developing science on the role of TEER in the management of patient with significant symptomatic MR.

Outstanding CED Questions

The medical field has learned more about possible differences in risks and benefits in older patients or patients with multiple comorbidities who are often underrepresented in clinical trials through CED. CED allows understanding of differences in effectiveness across practice settings or providers.

With the data underpinning FDA-approval of FMR indications for the MitraClip device coming significantly from one study that enrolled 302 patients to the device intervention group, the same outcomes under CED study for DMR patients under the current NCD warrant additional data collection to evaluate generalizability and durability. Those outcomes include all-cause mortality, stroke, repeat mitral valve surgery or other mitral procedures, worsening mitral regurgitation, transient ischemic events (TIAs), major vascular events, renal complications, functional capacity, and quality of life. CED would allow access for patients that are currently subject to exclusion criteria. **Importantly, this would mean CMS could offer coverage to more patients with CED maintained than under the current proposal.**

Other aspects of care that could be studied are the exact types of contraindicated conditions CMS has proposed elsewhere in the memo. Data collection under CED would gather evidence on areas such as the utility of the device in patients with other comorbidities not studied in the original trials such as pulmonary hypertension, pulmonary disease, and with other coexisting valvular disease to better deploy care to patients for whom it will be most effective.

Development of Direct Quality Metrics for TEER Requires CED

Presently there are no validated metrics for the assessment of quality of care for patients undergoing TEER for either DMR or FMR. The development of risk-adjusted validated outcome measures and their incorporation into national management guidelines should be a top priority with four distinct goals:

1. Enable programs to improve, especially with national benchmarks.
2. Facilitate public reporting.
3. Allow the eventual sunseting of institutional volume requirements used as a surrogate for direct quality measures.

4. Allow the CMS Innovation Center to consider application of a composite outcome measure to the payment for care improvement program.

For this comprehensive approach to quality to be feasible for TEER, for both DMR and FMR, there must be a process of required data collection with an NCD with CED. The current CMS proposal will prevent the development of a quality metric for TEER and is an abandonment of CMS's commitment to quality care for beneficiaries.

Bifurcated Coverage of FMR and DMR

The societies are very concerned with the proposal, to eliminate national coverage for DMR as part of the new TEER policy that creates coverage for FMR. It is simply absent from the operative coverage language. The proposed decision memo notes that, "Due to the very low number of procedures, < 1 % of the Medicare population undergo TEER of the mitral valve for degenerative MR, and the published procedural volume recommendations from the professional societies, CMS believes coverage of TEER for degenerative MR is an appropriate determination made by the Medicare Administrative Contractors (MACs). The MACs are structured to be able to take into account local patient, physician and institutional factors, which are especially important when overall prevalence is very low."

The first rationale that services provided to less than 1% of the Medicare population do not warrant the structure and consistency across the country that an NCD provides for a complicated and costly intervention to preserve and improve patients' lives is puzzling, as many services governed by NCDs would fit that criterion while others performed more commonly are not governed by NCDs. Degenerative MR constitutes 70% of U.S. patients entered in the TVT Registry. In Europe, where FMR is approved, it still comprises 20% of TEER patients. Furthermore, treating primary MR often solves the underlying cardiac problem whereas in FMR TEER does not treat the primary condition, and though the patient symptomatically may improve, their left ventricular dysfunction remains. The impact on longitudinal outcome and readmissions remains ill-defined. As a result, TEER in the prohibitive risk DMR patient can often be a more complete solution than TEER for FMR.

The societies also struggle to understand the second rationale that published procedural volume recommendations made by professional societies eliminate a role for NCD coverage of DMR—clinical guidelines, best practices, and experience recommendations exist for many services that are covered under NCDs.

Dividing coverage in this manner is confounded by the fact that there is often significant difficulty in the medical community differentiating DMR from FMR. In fact, 15% of patients currently entered into the TVT Registry are classified as "mixed" disease. To leave these coverage decisions to local contractors would create needless confusion in determining patient coverage.

It is the societies' experience that NCDs are deployed when disparate coverage policies across contractors exist or are expected, when complex or novel or resource-intensive services are under consideration, or when concerns about overutilization/misutilization exist. Several of these considerations apply to TEER, the most important of which is the potential to limit access to therapy due to coverage. Clinicians have long bemoaned the challenges that inconsistent and inaccurate coverage creates, requiring documentation and phone calls to navigate inconsistent policies. Sometimes patients are referred to another state where coverage is more appropriate and allows a therapy the physician and patient agree is necessary. Local factors are not irrelevant, but **the societies believe in and affirm the value of having a floor for coverage for TEER for both FMR and DMR and urge CMS to revise the final NCD to include DMR coverage alongside FMR as was suggested in the original request for reconsideration.**

Support for Institutional Requirements

The societies support CMS's proposal to require certain volume standards and staffing infrastructure for facilities and clinicians as a surrogate for quality outcome measures as an important piece of the proposal. The proposed standards are essentially consistent with those delineated in the 2019 expert consensus document, and the societies support the proposed volume standards. These standards increase the likelihood of an environment with a significant care infrastructure that will produce quality outcomes and access to care. **Ninety percent of the U.S. population is within a hospital referral region that has a center with the volume threshold needed for appropriate team evaluation.**³ The societies recognize not all stakeholders agree with this approach, and new data or analyses may support alterations to these volume standards. Any adjustment to volume requirements should be monitored and assessed to ensure optimal outcomes.

Furthermore, the societies support the language CMS has used that parallels the expert consensus document to describe the role on the care team of a heart failure specialist experienced in care and treatment of FMR. With the early development of heart failure as a designated specialty, it is appropriate at this time to not require more specific training or board certification that would potentially bar many experienced cardiologists with significant expertise in advanced heart failure as formal education opportunities remain modest.

Finally, the societies acknowledge that excellent procedure performance must be balanced with beneficiaries' access to care. Indeed, this equilibrium is usually a fluid and dynamic situation as technology and operator experience and expertise evolves and as more patients present for treatment. The elimination of CED precludes the ability to inform the medical community and payers as to whether the consensus standards are correct and whether they need to evolve and change over time.

³ Vemulapalli S, et al. JAMA Cardiol. 2019;4(11):1149–1155.

Recommended Adjustment to Contraindications and Indications

The proposed NCD includes seven contraindications that appear to be exclusion criteria taken from the COAPT trial. Such criteria are not meant to eliminate the possibility of future patient care, but to better account for confounding factors in a highly controlled clinical trial. Certainly, these are all examples of complicated patients who may be less likely to benefit from intervention than others without these comorbidities. However, applying them as absolute contraindications to the NCD will prevent some patients who would benefit from TEER from receiving this important therapy. For instance, some patients prescribed inotropes on a short-term basis would also be excellent candidates for TEER. These are decisions physicians and patients are capable of making together and the societies recommend these be removed as *absolute* contraindications. Instead, these are the exact types of patients and questions that can be better understood and answered through CED as has been done with other therapies. The medical field can learn a great deal through the collection of real-world evidence to improve both patient selection and procedural care through this mechanism, but only if CED is reinstalled.

Conversely, the NCD includes five inclusion indications that all moderate-to-severe or severe FMR patients on guideline-directed medical therapy must meet. Left ventricular ejection fraction and left ventricular end-systolic dimension stem from the FDA approval order for the device FMR indication. Cardiomyopathy and heart failure classification status were COAPT trial inclusion criteria. These indication criteria are reasonable at the current time for the evidence base available for TEER technology.

Rather than create such an explicit list of contraindications and indications, **the societies strongly recommend that CMS link coverage to use of FDA-approved devices for FDA-approved indications.** This is an approach CMS has used elsewhere that allows for the flexibility of new FDA indications to be incorporated seamlessly without additional reconsiderations. It is already in place for the existing TMVR coverage, as well as other NCDs, and has worked well. It would eliminate the need for overly prescriptive coverage criteria, allow and encourage the study of real-world patients through CED, and avoid repetitive reconsiderations as technology and evidence evolve.

Other Considerations

TEER Definition

In the original reconsideration request, the societies expressed uncertainty about how best to avoid confusion in the field about transcatheter mitral valve repair and replacement, both often referred to as TMVR. With only one device approved for either therapy at this point, revising the title of this policy to specifically address TEER therapy seems sensible at this time. It anticipates future therapies that utilize different mechanisms of repair or replacement and suggests those will also need to be addressed through separate NCDs. However, as implied in the 2019 expert consensus document, should CMS instead wish to design an NCD that can be evergreen as discussed above, the original recommendation made in the reconsideration request for a policy that addresses the broad category of

transcatheter mitral valve *therapy* with coverage consistent with FDA-approved indications is preferable as it would avoid the need for additional reconsiderations to add devices or indications.

Face-to-face visits

The existing NCD for DMR patients includes a requirement for face-to-face evaluation by both the interventional cardiologist and the cardiac surgeon on the heart team to consider the patient's suitability for surgical repair, TEER, medical therapy, or palliative therapy. For FMR, this requirement was incorrectly carried forward to this NCD, and the societies recommend it be removed for the reasons stated below. This should instead refer to the multidisciplinary heart team evaluation and its minimum composition of an interventional cardiologist, cardiac surgeon, and heart failure specialist, to adjudicate FDA-approved indications for FMR.

As explained in the 2019 expert consensus document, FMR patients “should first be evaluated and treated by a heart failure cardiologist who can then consider referral for MV intervention when clinically appropriate and after optimization of guideline directed medical therapy (including cardiac resynchronization therapy when indicated). Not all such HF patients with secondary MR would need to be seen individually by a cardiac surgeon, for example, unless therapy other than transcatheter edge-to-edge clip device repair (e.g., CABG surgery, tricuspid surgery, surgical AF ablation) were felt to be potentially indicated after initial MDT review.” This is in contrast to DMR patients. “Because surgical MV repair provides reduction of primary MR superior to edge-to-edge clip device repair, surgical consultation for these patients is critical to verify that operative risk is indeed high enough to warrant transcatheter intervention.”

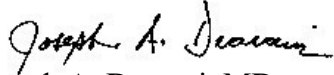
Stated a different way, FMR and DMR are different disease processes that are treated in different ways. Surgery is not necessarily part of the clinical pathway for pure FMR patients, typically limited to scenarios in which surgery for co-existing cardiac conditions has been planned (e.g. coronary bypass) as explained in the *2020 Focused Update of the 2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation*.⁴ Instead, these patients are commonly identified and managed by their primary cardiologist and/or heart failure specialist in concert with the entire heart team. Should the MDT deem that surgical options should be considered (e.g. evaluation for concomitant operations, mixed etiology patients, alternative therapies) then a face-to-face surgical consultation will be requested. This workflow inserts the MDT as the primary arbiter for FMR to adjudicate FDA-approved indications of therapy. A requirement for all FMR TEER candidates to execute an additional consult with a surgeon creates a burden to care and drains resources when surgeons are required to see these patients who would not otherwise be in their office.

Thank you for your consideration of these comments. The societies look forward to working with you and your team during the reconsideration process and are available to

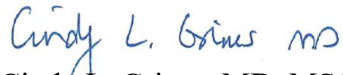
⁴ Bonow, et al. J Am Coll Cardiol. 2020 May, 75 (17) 2236-2270.

provide additional information or answer questions along the way. Please contact James Vavricek at jvavricek@acc.org or 202-375-6421 with any requests.

Sincerely,



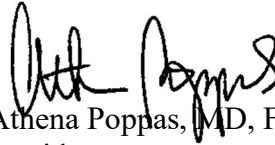
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