Duke | MARGOLIS CENTER *for* Health Policy

VIA ELECTRONIC SUBMISSION

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

RE: Proposed National Coverage Determination for Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (CAG-00438R)

Dear Director Syrek-Jensen,

The Robert J. Margolis, MD Center for Health Policy at Duke University (Duke-Margolis) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed national coverage determination ("Proposed NCD") captioned above.

The Duke-Margolis Center generates and analyzes across the spectrum of health policy and supports the triple aim of better care, better health, and lower cost. A core mission of the Center is to focus on increasing the value of biomedical innovation to patients. Center experts are engaged in policy research and development efforts to improve the processes and infrastructure needed at CMS to ensure efficient access to new and innovative technologies – including challenges related to coding, coverage, and payment. Key to this work is understanding the performance of health technologies in real-world clinical care through standardized data collection on safety and outcomes.

Duke-Margolis supports the Proposed NCD's goals to expand coverage of TEER for the treatment of functional mitral regurgitation. Duke-Margolis is, however, concerned that the proposed policies for both clinical indications, functional mitral regurgitation (FMR) indication and degenerative mitral regurgitation (DMR), do not include a formal coverage with evidence development (CED) framework. We believe CED is a valuable mechanism to address uncertainties regarding the clinical data supporting the FMR indication, and the uncertainty regarding the long-term outcomes and durability of the therapy in the DMR indication.

Our comments are guided by the following key principle: Since 2006, CMS has used its authority under Section 1862(a)(1) (A) and Section 1862(a)(1) (E) of the Social Security Act to mandate evidence development as a condition of coverage for certain medical products in the context of research conducted by the Agency for Healthcare Research and Quality.[1] Since then, CED has been a crucial tool in ensuring a wide diffusion of innovative technologies to the Medicare population when there may be uncertainty regarding long-term outcomes, on how well an intervention works in real-world practice settings, on durability, and to determine if there are important subpopulation effects.

CED allows patients to benefit from promising interventions that warrant additional evidence development. It has the potential to provide beneficiaries with more or earlier access to a treatment that is reasonable and necessary, while developing better evidence to inform optimal care decisions. By

promoting continued evidence development under real world settings, it helps to address questions that are not informed through clinical trials, such as long-term outcomes and effectiveness, determining the best value for the therapy, and collecting clinical evidence across subgroups of patients or indications. While CED is not meant to be a cost containment mechanism, it helps promote the use of treatments in Medicare beneficiaries who are more likely to benefit, which can be an important tool for increasing value and avoiding unnecessary costs in Medicare.[2]

CMS first provided coverage for transcatheter mitral valve repair (TMVR; now proposed to be renamed to TEER) in August 2014 under the CED framework for DMR when furnished according to an approved FDA indication.[3] Providers were able to fulfill CED requirements by enrolling in the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy (TVT) Registry. The TVT registry was created by a collaboration between the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC) and was approved by CMS to meet the registry requirements outlined in the NCDs for TMVR (NCD 20.33) in 2014 and transcatheter aortic valve replacement (TAVR) in 2012 (NCD 20.32). Data from the TVT Registry has been vital for post-market surveillance of TEER, evaluating real world effectiveness, and identifying the operator and institutional criteria that inform therapeutic benefit.

Duke-Margolis Comments on Specific Provisions of the Proposed NCD

Coverage proposal for FMR

CMS's analysis notes that evidence from the Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation (COAPT) trial, observational studies, and Medicare claims indicate that TEER for FMR is a promising treatment for Medicare patients. However, CMS notes that "evidentiary gaps remain regarding patient, interventionalist, and facility characteristics that would optimize the risk/benefit balance for TEER in Medicare beneficiaries."[4] Further, CMS's analysis notes that the observational studies do not reconcile discrepancies between the COAPT and Mitra-FR RCTs, and reflect "inconsistent procedures across studies, inconsistent reporting on prescribing and adherence to GDMT, incomplete follow up resulting in under-reporting of adverse events/mortality, varied procedural experience across sties, and varied time points across patients for data collection."[4]

While CED is notably absent in the proposed coverage decision, CMS does specify specific clinical research questions that should be addressed in future evidence generation. These research questions include patient selection criteria, long term effects, and 1-year follow up of specific clinical endpoints. Although it is encouraging that CMS continues to promote evidence development, and provides guidance on specific research questions, we are concerned that absent a CED framework, CMS will find it challenging to promote voluntary data reporting and reconcile data captured across multiple studies.

Per the current NCD 20.33, all TEER procedures (for DMR) are captured in the TVT registry. However, as CMS notes, these procedures are currently received by <1% of the Medicare population.[4] A significantly larger percentage of Medicare beneficiaries could be appropriate for TEER for FMR under the proposed coverage criteria, which may greatly expand the number of hospitals that provide the therapy. By removing conditional coverage, it is less likely that hospitals will newly enroll into the TVT

registry. Although the registry creates valuable evidence, it is costly and cumbersome for many hospitals and has limitations.[5]

These are valid concerns for hospitals. However, we believe that there is an opportunity to address operational limitations in the TVT registry by improving electronic data collection methods and streamlining data collection to enable broader patient access and lessen the burden on health care providers. If CMS continues CED under the NCD, there will be incentives for hospitals and the TVT registry to approach data collection that builds off advanced data systems for real world evidence, a less costly and a more effective alternative compared to the current registry. However, by removing the CED requirement there may be little motivation for stakeholders to make these improvements.

Additionally, individual clinical studies could resolve many of the questions that CMS identifies. However, without CED there is less incentive to do those studies, and, as CMS notes in their evidence review for TEER for FMR (CAG00438R) as well as DMR (CAG00438N), there are inherent issues in reconciling data across multiple studies. Per the 2014 NCD for TMVR, coverage under CED ensured that all Medicare patients that receive the therapy would be enrolled in a single national, auditable database. The advantages of a *single* national registry (or database) include:

- enabling direct comparison across all TEER devices, which will encourage technological improvements and clinical choice;
- analyzing all patients treated by different subgroups and provider types, removing any sample bias based on single institutions like centers for excellence;
- studying durability and long-term effects on a predictable timeline across all patients and subgroups;
- developing a large study population that can help identify and analyze patient, practice, and facility level variables that impact outcomes; and
- developing benchmarks for quality of care and outcomes.

As CMS notes in their analysis of the evidence for FMR, real world outcomes may not replicate those achieved in the COAPT trial, which raises questions about the generalizability of the results.[4] CMS addresses these concerns by issuing coverage criteria to follow the inclusion criteria of the COAPT trial, however, specifying similar inclusion criteria alone may not be sufficient to replicate the same outcomes. COAPT trial was performed under a strict set of clinical trial circumstances that cannot be reproduced in the real world. The trial specified close involvement of heart failure specialists to maximize medical therapy, echocardiographic core lab adjudication on the severity of mitral regurgitation, and careful pre- and peri-procedural screening of the valve anatomy and other measures. Continued evidence development is important to identify the patient population that can benefit from TEER therapy.

Coverage proposal for DMR

CMS has proposed that TEER for the DMR indication, which has been covered under a CED framework since August 2014, will now have coverage decisions made by local MACs. CMS notes that there is now sufficient evidence to make a coverage determination and due to the low volume of procedures, MACs are better equipped to make coverage decisions based on their understanding of "local patient, physician, and institutional factors, which are especially important when overall prevalence is low."[4]

While there has been a great deal of evidence on the effectiveness of TEER for DMR, Duke-Margolis believes that there are still questions regarding the long-term health outcomes of patients, as well as the durability of the therapy beyond five years. Continued data collection through a modernized TVT registry that obtains critical data more efficiently would address these questions. By entrusting local MACs on coverage criteria, future data collection will be limited since MACs cannot enforce CED. Even if a local MAC requires CED, the data may be inconsistent and vary among each jurisdiction. TEER needs reliable and efficient evidence development on long-term outcomes, on how well the intervention works in particular practice settings, and important subpopulation effects.[2]

Multiple coverage policies for different indications, enforced by multiple authorities is operationally challenging. It will be particularly cumbersome for the MACs to determine the indication for each claim and they will need guidance on standardizing across regional areas. Further, the absence of a systematic and predictable approach for coverage and approval can result in additional administrative burdens on health care providers. Finally, in the event there are differing coverage criteria across MAC jurisdictions, there will be uneven coverage for an established procedure and will be counter to goals of equal access to care.

Conclusion

Part of CMS's charge to improve the health and quality of life of its beneficiaries is linked to ensuring adequate and equitable access to medical therapies, especially with potential transformational technologies. CED achieves this through careful and streamlined monitoring of use of the technology in the real world with the added safety and patient protections provided by expert clinicians in facilities that furnish an appropriate environment with data collection.[5]

Given the conflicting evidence of the therapeutic benefit of TEER on heart failure patients, CED is a reliable means of collecting standard, specific data across all providers. Collecting data from the entire population in a consistent, timely, and transparent manner will help with better understanding safety signals and risk factors. This will result in practice improvements, future device innovations, and improved health outcomes.

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The Duke-Margolis Center appreciates CMS's consideration of our comments, and the Administration's support for advancing high-value, affordable healthcare. We and our colleagues would be pleased to provide more information on these issues if that would be helpful.

Sincerely,
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