July 30, 2020

Ms. Seema Verma

Administrator

Centers for Medicare & Medicaid Services

CC: Lead Analyst -- Sarah Fulton, MHS

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Dear Administrator Verma,

Heart Valve Voice US is a nonprofit patient advocacy organization that provides a united voice for people living with heart valve disease. We advocate for early detection, meaningful support, and timely access to appropriate treatment for all people affected by heart valve disease.

We welcome the proposed National Coverage Determination (NCD) from the Centers for Medicare & Medicaid Services (CMS) recognizing that Transcatheter Edge-to-Edge Repair (TEER) for functional mitral valve regurgitation is reasonable and necessary. Mitral valve regurgitation is the most common form of valvular disease, affecting an estimated 9.3 percent of the population age 75 or over[[1]](#footnote-1). This proposed NCD represents an important step forward for these patients.

We are generally supportive of the removal of the “Coverage with Evidence Development” designation but have some concerns about ongoing data collection, which we see as essential, as well as the future ability to cover additional conditions without supplementary evidence.

Our comments are focused on three areas: the limited nature of this NCD, both in terms of conditions covered and future application; the continued requirement for burdensome “face-to-face” appointments when telehealth has proven to be more than sufficient; and the ongoing surgical volume requirements for new and existing centers that have no scientific basis, are anti-competitive, and only serve to limit patient access.

We appreciate the Centers for Medicare & Medicaid Services’ (CMS) thoughtful consideration and adoption of recommendations from advocacy organizations representing patients and family caregivers.

**Comments on Proposed National Coverage Decision**

***Scope of NCD***

Heart Valve Voice US, along with many other concerned entities, had anticipated a broader NCD, potentially covering a range of emerging mitral valve technologies, including transcatheter mitral replacement devices. We believe such an approach would facilitate ease of access and coverage for patients, while also providing a predictable reimbursement pathway for manufacturers. Currently, according to clinicaltrials.gov, there are at least 15 trials underway in the United States for transcatheter devices to treat mitral regurgitation. Surely, CMS would not seek to undergo the NCD process for each of these devices that ultimately receives FDA approval. Such a regime limits patient access to the latest and most appropriate technologies while creating uncertainty in the medical community.

Further, under this NCD, CMS specifies seven conditions for which treatment of FMR is not covered even though the device is FDA approved for such use. The limitations will exclude coverage for TEER in FMR patients with advanced heart failure and other conditions who may not have other effective treatment options for symptom relief. While evidence on the benefit of TEER for these populations continues to develop, we are concerned that an overly restrictive NCD may not provide sufficient flexibility and will necessitate additional coverage decisions or reconsiderations to allow coverage for additional categories of FMR patients or analogous therapies.

The results of the Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPTTM) trial, as well as most observational studies, illustrate clear improvements in hospitalization rate and mortality, especially in periods exceeding one-year post-procedure.[[2]](#footnote-2) As a result of these findings, the U.S. Food and Drug Administration (FDA) approved TEER In March 2019 for heart failure (HF) patients who have moderate-to-severe or severe FMR despite treatment with optimal medical therapy. The CMS decision supports this determination and allows Medicare patients access to TEER to treat FMR.

**We strongly urge CMS to cover FDA-approved, on-label use for devices in this broader category, in a more timely manner, and consistent with the approach taken with the Transcatheter Aortic Valve Replacement (TAVR) NCD. We also encourage CMS to change the name of the NCD to encompass future therapies.**

***Remove “Face-to-Face” Examination Requirement***

We understand the CMS definition of “face-to-face” to mean “in-person.” If this is, in fact, the meaning, we ask that the requirement either be removed entirely or the definition be clearly modified to include telehealth interactions, either through video or other means. During the Coronavirus Disease 2019 (COVID-19) public health emergency (PHE), waivers have been provided to enable the widespread use of telehealth, including waivers for face-to-face examination before a TEER procedure. While these flexibilities are temporary and tied to the PHE, the widespread uptake and increased comfort level with telehealth by both providers and patients has created significant support for a permanent adoption of telehealth.

Requiring patients to attend multiple, in-person appointments, often brief and with limited value, imposes a tremendous burden that can be eliminated through the use of existing technologies and telemedicine. Candidates for TEER will already be under the care of an interventional cardiologist and have received an echocardiogram and other appropriate tests to ensure their suitability for the procedure. Advances in imaging, such as advanced echocardiograms and coronary computed tomography angiogram (CTA) provide the heart team with key information without necessitating an in-person visit. We also know that travel time is an important, often determining, factor in a patient’s decision to seek surgical care, and is twice as important as following a referral or hospital affiliation *(Advisory Board)*.

Research on patients who have received Transcatheter Aortic Valve Replacement is instructive here. On average, patients make 26 physician visits and wait 216 days between diagnosis and treatment *(2016, IQVIA)*. Surely, it is not only in the best interest of patients, but also CMS to streamline this process without compromising patient safety or outcomes. In many cases, even an initial patient assessment could be satisfactorily conducted via telemedicine. Advances in remote monitoring, such as EKG, heart rate and oxygen saturation levels can also be effectively deployed pre- and post-procedure.

Going forward, we urge CMS to weigh the value of such in-person interactions versus the potential burden to patients, especially if multiple in-person appointments are required. As we have seen both before and during the COVID-19 pandemic, **telehealth offers significant advantages to patients of all types, including and especially older Americans with mobility and other age-associated health conditions. We believe telehealth is not a trend but an important tool to facilitate safe, convenient, efficient access for patients.**

We realize telehealth and payment parity is a larger issue within CMS; addressing it here in the patient context is a starting point.

***Volume and Program Requirements for New and Existing TEER Programs***

CMS continues to rely on unrelated surgical volume requirements for both existing and potential new TEER programs. We are concerned that such requirements will discourage the initiation of new programs in areas of need. Of note, this NCD was drafted prior to the publication of two high-quality studies (one in the [*Journal of the American Heart Association* [JAMA]](about:blank)[[3]](#footnote-3) and the other in the [*Journal of the American College of Cardiology*](about:blank) *[JACC][[4]](#footnote-4)*) that demonstrate there is no relationship between mitral valve surgical volumes and transcatheter mitral valve repair outcomes, including survival, rehospitalization or mitral valve re-intervention. Such surgical volume requirements needlessly restrict patient access, especially in rural areas of the Midwest and Southeast and among Black and Hispanic populations. We trust that CMS will consider this emerging body of evidence to reconsider such volume requirements.

Further, the draft NCD creates barriers to access by instituting separate surgical volume requirements for existing and new TEER programs. The existing NCD for TMVR requires a surgical program to perform ≥ 25 total mitral valve surgical (MVS) procedures for severe MR per year of which at least 10 must be mitral valve repairs. The proposed NCD introduces requirements dependent upon whether the TEER program is new (40 MVS procedures in the preceding year) or existing (20 MVS procedures per year or 40 every two years). The two studies referenced above illustrate that these distinctions are unconnected with clinical outcomes and that surgical volume minimums should be aligned at 20 procedures per year (or 40 over two years) for both new and existing TEER programs. The JACC study showed that while there was a connection between hospitals with extremely low (1-18) surgical mitral valve volume and in-hospital TEER mortality, this association dissipated for hospitals performing a moderate (19-51) volume of MVS procedures.[[5]](#footnote-5)

These results illustrate that a 40 MVS procedure minimum for new TEER programs would stifle competition and create a de facto cap on the number of providers performing TEER. Smaller, rural hospitals would be disproportionately impacted, further reducing access for these patients, and necessitating inconvenient and risky travel to receive care. Alternatively, patients may forego the procedure entirely, further compromising their health.

**The new minimum surgical procedure thresholds for both new and established TEER programs are not evidence-based and should be eliminated. We urge CMS to eliminate the separate, higher mitral valve surgical requirements for new TEER programs in the final NCD.**

***Additional Issues***

*Participation in data registries*

The current data registry system for transcatheter valve technologies is cumbersome, opaque, inaccessible, and of little value to patients. We understand that CMS is reluctant to continue to require reporting to a data registry without CED. However, this data is critical to evaluate and monitor the ongoing quality and safety of these technologies, as well as patient outcomes. CMS should require data reporting requirements for TEER procedures (and potentially others covered under a final NCD) as a condition of coverage. The data reported should include outcomes that can be evaluated for the influences of access, race and sex.

CMS should work with patient organizations, the TVT Registry, providers and manufacturers to streamline reporting requirements in order to reduce administrative burden while also improving the utility of the data. Ultimately, the data must be publicly accessible. Patients – and CMS – should not be limited to analyses and data published in medical journals.

**If the goals of simplified reporting, increased transparency, broader access and greater utility cannot be accommodated through the current TVT Registry structure, then CMS should consider an alternative reporting mandate to a patient-centered registry.**

*National vs. Local Coverage Decisions*

We disagree with CMS’s proposal to defer to Medicare Administrative Contractors (MACs) on coverage decisions for degenerative mitral regurgitation (DMR) within their respective jurisdictions. We are concerned that local coverage determinations (LCDs) could negatively impact access for patients with DMR if some MACs opt for more restrictive coverage policies. A patient’s access to care options should not be compromised because of the state or zip code in which they live.

While we appreciate there is a relatively limited volume of DMR patients, this should not be used as justification for transferring coverage decisions for DMR to MACs. The previous NCD for TMVR was applicable to DMR patients (under CED). Uniformity in coverage should be the goal whenever feasible. As such, **we recommend that CMS include coverage of DMR in the NCD to promote consistency of access and coverage.**

*Composition of Heart Team*

TEER is a complex procedure. We concur with the value of a collaborative, multidisciplinary heart team in coordinating the care of a patient. We appreciate CMS’ reference to shared-decision making (SDM) and the agency’s call for standardized decision aids or tools using the [National Quality Forum’s (NQF) published standards](about:blank). TEER is a prime example where patient preferences, along with scientific evidence, should be considered to establish the appropriate composition of the heart team.

The proposed NCD places undue emphasis on the role of a cardiac surgeon in the care of TEER patients. The standard of care for patients with advanced heart failure in need of mitral valve repair for FMR is guideline-directed medical therapy, not surgery. These patients are frequently too sick to tolerate surgery, let alone invasive open-heart surgery, which has not demonstrated a mortality or hospitalization benefit in this population.[[6]](#footnote-6) Until the recent introduction of TEER, medical therapy was the sole treatment option for these patients.

While cardiac surgeons may be included in the heart care team, we believe a requirement for a second in-person examination by a surgeon places an undue burden on patients and creates an unnecessary barrier to care. We encourage CMS to consider the proper composition of a multidisciplinary heart team to include some combination of an interventional cardiologist, echocardiographer, cardiac surgeon and heart failure specialist, or other specialists who may be pertinent to the patient’s case.

**We encourage CMS to support the determination of appropriateness for TEER by including a heart failure specialist on the multidisciplinary heart team.**

*Clinical Trials*

**We support CMS’s use of non-randomized controlled clinical trial studies in developing the proposed NCD for TEER**. In general, we believe CMS should defer to the clinical trial data used in connection with the FDA approval of a technology. However, if additional clinical trials are required, non-randomized controlled studies are the only approach that should be considered in this situation given the ethical and practical considerations.

**Conclusion**

Mitral regurgitation effects more than 5.2 million Americans, 1.7 million of whom are age 75 or older[[7]](#footnote-7). This proposed national coverage decision will have a positive impact on many Medicare beneficiaries.

We thank CMS for the constructive developments included in this NCD and trust that our comments will be given full consideration to advance patient interests.

Sincerely,

John Lewis

Executive Director

1. Nkomo VT, et al. Lancet. 2006;368:1005-11 [↑](#footnote-ref-1)
2. Stone, Gregg W., et al. *Transcatheter Mitral-Valve Repair in Patients with Heart Failure.* The New England Journal of Medicine. 13 Dec 2018. [https://www.nejm.org/doi/full/10.1056/NEJMoa1806640](about:blank) [↑](#footnote-ref-2)
3. Vemulapalli, Sreekanth, et al. *Mitral Valve Surgical Volume and Transcatheter Mitral Valve Repair Outcomes: Impact of a Proposed Volume Requirement on Geographic Access*. Journal of the American Heart Association. Vol. 9, No. 11. 27 May 2020. [https://www.ahajournals.org/doi/10.1161/JAHA.119.016140](about:blank) [↑](#footnote-ref-3)
4. Barker, Colin M., et al. *Association Between Intuitional Mitral Valve Procedure Volume and Mitral Valve Repair Outcomes in Medicare Patients*. Journal of the American College of Cardiology. Vol. 75, No. 11. March 2020.[https://www.onlinejacc.org/content/75/11\_Supplement\_1/1320](about:blank) [↑](#footnote-ref-4)
5. Barker, Colin M., et al. *Association Between Intuitional Mitral Valve Procedure Volume and Mitral Valve Repair Outcomes in Medicare Patients*. Journal of the American College of Cardiology. Vol. 75, No. 11. March 2020.[https://www.onlinejacc.org/content/75/11\_Supplement\_1/1320](about:blank) [↑](#footnote-ref-5)
6. Bonow, Robert O., et al. *2020 Focused Update of the 2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation.* Journal of the American College of Cardiology. Vol. 75, Issue 17. May 2020. [https://www.onlinejacc.org/content/75/17/2236](about:blank) [↑](#footnote-ref-6)
7. Nkomo VT, et al. Lancet. 2006;368:1005-11 [↑](#footnote-ref-7)