

July 30, 2020

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
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Dear Administrator Verma,

The undersigned organizations appreciate the opportunity to provide input on the proposed national coverage decision (NCD) memo for mitral valve Transcatheter Edge-to-Edge Repair (TEER), previously referred to as Transcatheter Mitral Valve Repair (TMVR). The TEER procedure has shown promising outcomes for clinically appropriate patients and provides a minimally invasive treatment option for patients who are not candidates for surgical repair.

The undersigned coalition appreciates the Centers for Medicare & Medicaid Services' (CMS) thoughtful consideration and adoption of recommendations from advocacy organizations representing patients, providers, and family caregivers in the proposed TEER NCD. These changes will expand coverage and advance innovative treatment for mitral regurgitation (MR) for Medicare beneficiaries. However, we are concerned about the deep-seated inequities spotlighted by the Coronavirus Disease 2019 (COVID-19) pandemic. We remain concerned about selected program eligibility requirements and the unintended consequences of imposing a minimum number of annual surgical and interventional cardiac procedures to maintain a TEER program. These policies may restrict patient access to TEER programs, further exacerbating systemic inequities in health outcomes experienced by racial and ethnic minorities and populations in underserved areas.

### **Comments on the Proposed National Coverage Decision**

#### *Coverage of TEER for functional mitral regurgitation*

**We applaud CMS's decision to expand coverage of TEER to patients with functional mitral regurgitation (FMR).** The results of the *Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPT™)* trial, as well as most observational studies, illustrate clear improvements in hospitalization rate and mortality, especially in periods exceeding one-year post-procedure.<sup>1</sup> 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.

In the proposed NCD, CMS provides seven conditions for which treatment of FMR is not covered. The limitations will exclude coverage for TEER in FMR patients with advanced heart failure and other

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<sup>1</sup> 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>

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conditions who may not have other effective treatment options for symptom relief. While evidence on the benefit of TEER for these populations is under development, we are concerned that the proposed restrictions may not allow sufficient flexibility. An overly restrictive NCD would require additional coverage decisions or reconsiderations to allow coverage for additional categories of FMR patients or analogous therapies. **We encourage CMS to cover FDA-approved, on-label use for devices in this broader category. We also encourage CMS to change the name of the NCD and use inclusive terminology to reflect other transcatheter mitral valve repair interventions.**

### *Multidisciplinary heart care teams and face-to-face requirements*

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](#).

However, the NCD introduces several conditions of coverage that create unnecessary barriers to care. In this section, we discuss a more appropriate role for cardiac surgeons in the heart care team for TEER patients. We also address the need for flexibility in relation to the face-to-face examination requirement.

The proposed NCD places undue emphasis on the role of a cardiac surgeon in the care of TEER patients with FMR. 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.<sup>2</sup> Until the recent introduction of TEER, medical therapy was the sole treatment option for these patients.

In the COAPT trial, independent face-to-face visits with both an interventional cardiologist and a cardiac surgeon were required.<sup>3</sup> However, that was in the context of a structured clinical trial where variables were tightly monitored to isolate the impact of the intervention. In the setting of community-based care, not all trial-based requirements are appropriate.

While cardiac surgeons should be included in the heart care team, we believe a requirement for a second in-person examination by a surgeon creates an unnecessary barrier to care. The risk of a TEER procedure requiring conversion to heart surgery (0.7 percent surgical bailout rate)<sup>4</sup> is low, mitigating the need for a surgical examination requirement. While an in-person consult with a surgeon may be appropriate for selected patients, these results show that it should not be mandated for all patients.<sup>5</sup>

<sup>2</sup> 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>

<sup>3</sup> 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>

<sup>4</sup> Sorajja, Paul, et al. *Outcomes with Transcatheter Mitral Valve Repair in the United States: An STS/ACC TVT Registry Report*. Journal of the American College of Cardiology, Vol. 70, Issue 19, 7 Nov 2017. <https://www.sciencedirect.com/science/article/pii/S0735109717396730?via%3Dihub>

<sup>5</sup> 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>

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**We recommend that CMS remove the requirement for a face-to-face examination with a cardiac surgeon. Instead, we encourage CMS to support the determination of appropriateness for TEER by including a heart failure specialist on the multidisciplinary heart team.**

**We also encourage CMS to allow a telehealth visit to satisfy the requirement for a face-to-face examination requirement.** Candidates for TEER will be under the care of a multidisciplinary heart team and undergo an echocardiogram and other appropriate tests to ensure their suitability for the procedure. CMS should avoid being overly prescriptive in coverage requirements to accommodate advances in clinician practice and minimize patient burden. For example, during the COVID-19 public health emergency (PHE) waivers have been provided to enable the widespread use of telehealth, including waivers for face-to-face examinations before a TEER procedure and payment parity between telehealth and in-person visits. While these flexibilities are temporary and tied to the PHE, the widespread uptake and increased comfort level with telehealth by both providers and the public has created significant support for a permanent extension of these waivers. Some states, such as Colorado and Idaho, have already permanently eliminated restrictions on telehealth use.<sup>6</sup> **We encourage CMS to continue payment parity for telehealth visits after the conclusion of the COVID-19 PHE.**

#### *Volume and program requirements for new and existing TEER programs*

The proposed NCD for TEER for FMR includes increased, unnecessary conditions of coverage that would require hospitals to perform a minimum number of surgical procedures. These surgical requirements have little relation to the ability of a hospital to successfully perform TEER. While thoracic specialty societies may favor volume requirements, **these restrictions do not help patients with advanced heart failure in need of mitral valve repair.** Two recently published studies (one in the [Journal of the American Heart Association \[JAHA\]](#) and the other in the [Journal of the American College of Cardiology \[JACC\]](#)) conclusively demonstrated there are no established connections between mitral valve surgical volume and one-year rates of survival, rehospitalization or mitral valve reintervention.<sup>7, 8</sup>

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  $\geq 25$  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

<sup>6</sup> Livingston, Sherry. *Some States Cement COVID-19 Telehealth Expansions*. Modern Healthcare. 08 Jun 2020. <https://www.modernhealthcare.com/law-regulation/some-states-cement-covid-19-telehealth-expansions>.

<sup>7</sup> 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>

<sup>8</sup> Barker, Colin M., et al. *Association Between Institutional 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](https://www.onlinejacc.org/content/75/11_Supplement_1/1320)

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moderate (19-51) volume of MVS procedures.<sup>9</sup> Further, the JAHA study showed that implementing an annual MVS procedure minimum of 40 would disproportionately limit access to TEER in the Midwest and Southeast, causing an outsized restriction on access for Black and Hispanic populations.<sup>10</sup> These results illustrate that a 40 MVS procedure minimum for new TEER programs would institutionalize a protectionist policy and likely prevent the use of the procedure beyond the current base of providers. Imposing unnecessary criteria will limit access – including to smaller and rural hospitals – by barring otherwise qualified hospital heart teams from utilizing TEER for appropriate patients. The proposed minimum surgical procedure thresholds for both new and established TEER programs are not evidence-based, will limit patient access, and should be reevaluated. **We urge CMS to eliminate the separate, higher mitral valve surgical requirements for new TEER programs in the final NCD.**

The evolution of heart valve disease treatment to less-invasive options significantly affects the ecosystem of hospitals and specialty physicians who make a living treating these conditions. Thoracic surgeons have been saving heart valve disease patients for decades through open-heart surgery; however, interventional cardiologists perform most transcatheter procedures. Patients are stuck in the middle of a professional sea change in heart valve disease treatment involving the specialist clinician, and between major medical centers and smaller community-based and rural hospitals.

CMS' role is not to referee these provider issues, but to adopt an evidence-based coverage decision that will most benefit Medicare beneficiaries. By lowering the minimum MVS procedure threshold and separate program requirements included in the draft decision, CMS will ensure appropriate access to TEER and avoid reinforcing disparities for minority and rural populations.

### *Participation in data registries*

The proposed decision would allow for national coverage of TEER for FMR patients. As a result, requirements related to TEER's prior classification under coverage with evidence development (CED) would be eliminated, including mandatory participation in the TVT Registry.

Hospitals and care providers must fulfill extensive reporting requirements (including abstraction and reporting of data) to comply with the Medicare conditions of participation, which contribute to substantial administrative expenditures.<sup>11</sup> Given these requirements and the expense involved in reporting to the TVT Registry, it is unlikely that providers will provide registry data on a voluntary basis. However, the absence of a TEER data collection mandate will result in incomplete data reporting, which limits the ability to assess quality of care. Continued documentation of data on the long-term outcomes (including 30-day, one year, and post one-year) of TEER remains important and will help determine new indications. Patients and physicians should continue to be well-informed about the likely range of outcomes as TEER is performed in non-trial settings. Further, we applaud and agree with CMS that

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<sup>9</sup> 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](https://www.onlinejacc.org/content/75/11_Supplement_1/1320)

<sup>10</sup> 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>

<sup>11</sup> American Hospital Association. *Regulatory Overload: Assessing the Regulatory Burden on Health Systems, Hospitals, and Post-acute Care Providers*. Oct 2017. <https://www.aha.org/sites/default/files/regulatory-overload-report.pdf>

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broader evidence in predicting successful outcomes is warranted, particularly around the influence of access, race, and sex.

Consequently, **CMS should include post-market data collection as a coverage requirement to ensure measurement of quality outcomes and to support development or improvement of new or existing therapies.** CMS has previously finalized other NCDs with continued registry reporting requirements after ending CED.<sup>12</sup> **CMS should also work with providers and the TVT Registry to ensure that data collection requirements are streamlined<sup>13</sup> to reduce providers' data collection burden and participation costs.**

### *Accessibility of registry information to federal agencies and the public*

The lack of transparency and availability of registry data provides barriers to evaluating outcomes. In the NCD, CMS indicates the agency will continue to “assess patient outcomes through evidence published in the peer reviewed literature.” However, CMS and FDA should have the capability to monitor safety and efficacy outcomes on an ongoing basis, as well as differentiate between procedure types. For example, current code sets for Medicare claims data do not provide a way to differentiate between degenerative mitral regurgitation (DMR) and FMR. These data and other key outcomes information are only available through the TVT Registry. Patients and federal agencies have the right to understand how devices are performing. **To support this aim, CMS should require that registries provide regular reports (annually, at a minimum) to evaluate outcomes.**<sup>14</sup>

Further, the TVT Registry reports aggregate data only. Provider-specific information on TEER health outcomes is not publicly available. The TVT Registry website states that “Hospital-specific registry data is not publically [sic] available and the registry cannot provide data without written permission from the hospital to do so.”<sup>15</sup> Presumably, data for physicians employed or contracted by the hospital would be subject to the same restriction. However, it is more valuable to understand TEER outcomes by physician, rather than by facility, in making meaningful performance distinctions between providers.

We ask that CMS correct this lack of transparency in health outcomes in the final NCD. CMS already requires physician reporting for other quality metrics under Medicare's Quality Payment Program (QPP). In the QPP, CMS collects data through claims, registries, and provider attestations to support physician payment determinations. These data are publicly displayed on the [Physician Compare site](#) to help consumers make more informed decisions about their health care and to encourage clinical excellence. We acknowledge that public reporting may not currently be appropriate given the relatively limited volume of TEER procedures. **However, federal agencies should have access to registry data for TEER patients to support safety and efficacy monitoring efforts.**

Immediate reporting of these data are also already provided in New York State. Since 1989, the New York Department of Health (DOH) has published annual data on risk-adjusted mortality following

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<sup>12</sup> Centers for Medicare and Medicaid Services. *Lung Cancer Screening Registries*. 30 Jan 2020. <https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Lung-Cancer-Screening-Registries>

<sup>13</sup> Pew Charitable Trusts. *Medical Device Registries: Recommendations for Advancing Safety and Public Health*. Sept. 2014. <https://www.pewtrusts.org/-/media/assets/2014/09/device-registry-conference-report.pdf>

<sup>14</sup> Pew Charitable Trusts. *Medical Device Registries: Recommendations for Advancing Safety and Public Health*. Sept. 2014. <https://www.pewtrusts.org/-/media/assets/2014/09/device-registry-conference-report.pdf>

<sup>15</sup> STS/ACC TVT Registry. *Frequently Asked Questions*. <https://www.ncdr.com/WebNCDR/tvt/publicpage/faqs>.

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coronary artery bypass surgery by hospital and surgeon.<sup>16</sup> The state's Cardiac Surgery Reporting System (CSRS) was the first program in the country to produce public data on outcomes for cardiac surgery and is the nation's longest running program of its kind. DOH is advised in its activities by the Cardiac Advisory Committee (CAC), a group of independent, practicing cardiac surgeons, cardiologists and other professionals in related fields.

The goal of DOH and the CAC is to improve the quality of care related to cardiac surgery in the state. Providing hospitals and cardiac surgeons in New York with data about their own outcomes for these procedures allows them to examine the quality of care they provide and to identify areas needing improvement. This also allows patients and family caregivers to research data on Transcatheter Aortic Valve Replacement (TAVR) mortality outcomes in local hospitals. The program operates under the general authority of the DOH commissioner. As mentioned in previous comments on TAVR, **we know from the New York DOH that this level of transparency can be achieved, that providers and patients benefit significantly, and that better healthcare is the result. The TVT Registry should meet these aims.**

### *Designation of coverage decisions for degenerative mitral regurgitation to Medicare Administrative Contractors*

We disagree with CMS's proposal to defer to Medicare Administrative Contractors (MACs) on coverage decisions for treatment of 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. For example, a beneficiary in New York could be eligible for TEER, but an identical patient in New Jersey may not be covered if the MAC with jurisdiction has differing coverage criteria.

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. Uniformity in coverage should be the goal whenever feasible. Currently, there is a relative abundance of evidence regarding the safety and efficacy of TEER for DMR patients. As a result, **we recommend that CMS revise the NCD to incorporate coverage for TEER for patients with DMR.** In addition, we oppose re-imposition of DMR-specific volume requirements that existed in the prior TMVR NCD.

### *Inclusion of non-randomized controlled clinical trial study designs*

**We support CMS's use of non-randomized controlled clinical trial studies in developing the proposed NCD for TEER.** As mentioned in our previous comments, the prognosis among patients with heart failure and FMR on guideline-directed medical therapy alone is very poor. In the COAPT trial, approximately two-thirds of patients who had guideline-directed medical therapy alone (control group) died or were hospitalized for heart failure within 2 years.<sup>17</sup> The study found that the annualized rate of all hospitalizations for heart failure within 24 months was 35.8% per patient-year in the device group as compared with 67.9% per patient-year in the control group, and death from any cause within 24 months

<sup>16</sup> New York State Department of Health. *Cardiovascular Disease Data and Statistics*.

<https://www.health.ny.gov/statistics/diseases/cardiovascular/>

<sup>17</sup> Centers for Medicare and Medicaid Services. *National Coverage Analysis (NCA) Tracking Sheet or Transcatheter Mitral Valve Repair (TMVR) (CAG-00438R)*. 14 Aug 2019. <https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=297>.

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occurred in 29.1% of the patients in the device group as compared with 46.1% in the control group. Given the nature of the TEER intervention, it would have been unethical to blind the study.

### *Timeline for coverage decision*

We encourage CMS to shorten the timeframe between FDA approval of new indications and reviews of coverage determinations. We acknowledge that the review process likely experienced delays due to the COVID-19 pandemic. However, after the comment review period and issuance of the final NCD for TEER, approximately 18 months will have elapsed between FDA approval and finalization of Medicare TEER coverage for FMR. Given the potential for dramatically improved FMR patient outcomes as illustrated by trial data – and the lack of an alternative to TEER with similar clinical benefits – a more rapid process to ensure appropriate coverage for Medicare patients is warranted and necessary. Patient access to therapeutics should be prioritized once the safety and efficacy of a therapy for an indication has been established.

### **Conclusion**

We thank CMS for the many positive advances included in the proposed national coverage decision for TEER. Expanding coverage to patients with FMR and mandating shared decision-making by an interdisciplinary heart care team will ensure that TEER can be utilized for patients whom the procedure is likely to provide clinical benefit. At the same time, we ask CMS to revise the program eligibility requirements and criteria to ensure that access to high-quality TEER programs is available to the greatest number of Medicare beneficiaries.

We thank you for the opportunity to provide feedback on the proposed decision memo for TEER. If we can be of assistance in discussing these comments in greater detail, please contact us at (202) 688-1230 or [mward@agingresearch.org](mailto:mward@agingresearch.org).

Sincerely,

Alliance for Aging Research  
Association of Black Cardiologists  
Caregiver Action Network  
HealthyWomen  
Heart Valve Voice US  
National Hispanic Medical Association  
Mended Hearts  
Men's Health Network  
RetireSafe