Abbott
1399 New York Ave NW, Suite 200
Washington, DC 20005

T: +1 202 378 2023
F:+1 202 783 6631
Barbara.Calvert@abbott.com

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

RE: Comments on Proposed Decision Memo for Transcatheter Mitral Valve Repair (TMVR) (CAG-00438R)

Dear Ms. Syrek Jensen:

Abbott is pleased to submit comments on the proposed decision memo for transcatheter edge-to-edge repair (TEER) procedures to treat mitral regurgitation. Abbott appreciates that CMS has proposed coverage updates to TEER after FDA approval of an expanded indication for the MitraClip™ device.

Abbott is the manufacturer of the MitraClip™ System, the only FDA-approved TMV Repair device. Abbott initially received FDA approval for MitraClip™ on October 24, 2013 for the treatment of degenerative mitral regurgitation in patients at prohibitive risk for mitral valve surgery. On March 14, 2019, FDA approved an expanded indication for MitraClip™ to include the treatment of functional mitral regurgitation in heart failure patients when used with maximally tolerated guideline-directed medical therapy (GDMT).

The FDA approved indication for MitraClip™ is as follows:

- *The MitraClip™ System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.*

- *The MitraClip™ System, when used with maximally tolerated guideline-directed medical therapy (GDMT), is indicated for the treatment of symptomatic, moderate-to-severe or severe secondary (or functional) mitral regurgitation (MR; MR ≥*

Grade III per American Society of Echocardiography criteria) in patients with a left ventricular ejection fraction (LVEF) ≥20% and ≤ 50%, and a left ventricular end systolic dimension (LVESD) ≤ 70 mm whose symptoms and MR severity persist despite maximally tolerated GDMT as determined by a multidisciplinary heart team experienced in the evaluation and treatment of heart failure and mitral valve disease.[1]

Summary of Comments

Abbott supports the proposed expansion of coverage for Medicare beneficiaries with functional MR as it will provide access to a life-saving therapy[2]. MitraClip™ has been FDA-approved for seven years and has had robust real-world data collection during that time which confirmed the benefit to patients[3].

While Abbott agrees with expanding coverage to functional MR patients, there are a few changes we request in order to ensure appropriate access for patients in need of therapy. In light of recent evidence[4,5], we believe the proposed mitral valve surgical volume requirements are unreasonably high, would limit patient access, and do not improve patient care. We also believe that the addition of a coverage exclusion list for certain coexisting conditions is overly restrictive and CMS should rely on the heart team to determine patients "in whom existing comorbidities would preclude the expected benefit." As discussed in further detail below, Abbott supports continuation of CED as a pathway to extend coverage for beneficiaries with co-existing conditions, if CMS believes on-going data collection is needed.

Below is an abbreviated list of all the topics addressed in our comment, followed by a detailed discussion of each.

1. Abbott supports coverage for current FDA approved indications for TEER for the treatment of functional MR with the following recommendations:
    a) Remove coverage requirements that are included in the MitraClip™ FDA indication for functional MR patients as these are captured in "furnished according to an FDA-approved indication"
    b) Remove requirement for determination that mitral valve surgery will not be offered as a treatment option
2. Abbott supports retaining coverage for degenerative MR at the national level

[1] MitraClip™ NTR/XTR Clip Delivery System, Instructions for Use (March 2019).

[2] Stone GW, Lindenfeld JA, Abraham WT, et al. Transcatheter mitral-valve repair in patients with heart failure. *N Engl J Med* 2018; 379: 2307-18.

[3] Sorajja P, Vemulapalli S, Feldman T, et al. Outcomes With Transcatheter Mitral Valve Repair in the United States: An STS/ACC TVT Registry Report. *J Am Coll Cardiol*. 2017;70(19):2315-2327.

[4] Barker CM, Reardon MJ, Reynolds MR, Feldman TE. Association Between Institutional MV Procedure Volume and MV Repair Outcomes in Medicare Patients *J Am Coll Cardiol Intv*. 11 May 2020. 13(9), 1137-1139

[5] Vemulapalli S, Prillinger J, Thourani V, Yeh RW. Mitral Valve Surgical Volume and Transcatheter Mitral Valve Repair Outcomes: Impact of a Proposed Volume Requirement on Geographic Access *JAHA* May 27, 2020 [Epub ahead of print]

3. Abbott requests modification to certain operator and institutional requirements as follows:
    a) Remove / revise increased mitral valve surgery volume requirements for both hospital programs and cardiac surgeons, particularly given recently published analyses showing no relationship to TEER outcomes
    b) Clarify the annual transcatheter procedural volume requirement
    c) Modify procedural volume requirements (open mitral valve surgery and transcatheter intervention) into a single blended procedural volume requirement for MR interventions; separate volume requirements may have unintended consequences, particularly as the transcatheter space develops
    d) Remove all board eligibility or certification requirements to better align with TAVR NCD 20.32
4. Abbott supports the addition of a heart failure physician specialist as a required member of the heart team
5. Abbott requests modification of required face-to-face evaluations for every functional MR patient as follows:
    a) Remove required in-person surgical consult for every functional MR patient (may be conducted as needed per local heart team)
    b) Ensure appropriate flexibility for patient evaluations by removing strict face-to-face requirements and allowing alternatives to be considered (e.g., telemedicine)
6. Abbott requests modification or removal of the exclusion for patients with coexisting conditions as follows:
    a) Remove overly restrictive clinical trial exclusion criteria that are not included in the FDA-approved labeling as Contraindications
    b) Remove the exclusion for hemodynamic instability given published case studies and the need for further evaluation of this vulnerable patient population
    c) Remove the exclusion for coexisting tricuspid valve disease given Abbott's IDE trial studying tricuspid valve repair, which requires mitral valve disease to be treated first
    d) Remove the exclusion for chronic obstructive pulmonary disease (COPD) requiring home oxygen therapy or chronic oral steroid use given the frequency of MR requiring treatment in these patients as well as potential for further evaluation of this vulnerable population
    e) Remove the exclusion for advanced heart failure (HF) and planned cardiac surgery given the published results in TEER patients along the care continuum of heart transplant surgery
7. Abbott supports the scope clarification to TEER
8. Abbott supports CED and mandatory registry participation to provide access for patients with coexisting conditions excluded in the proposal

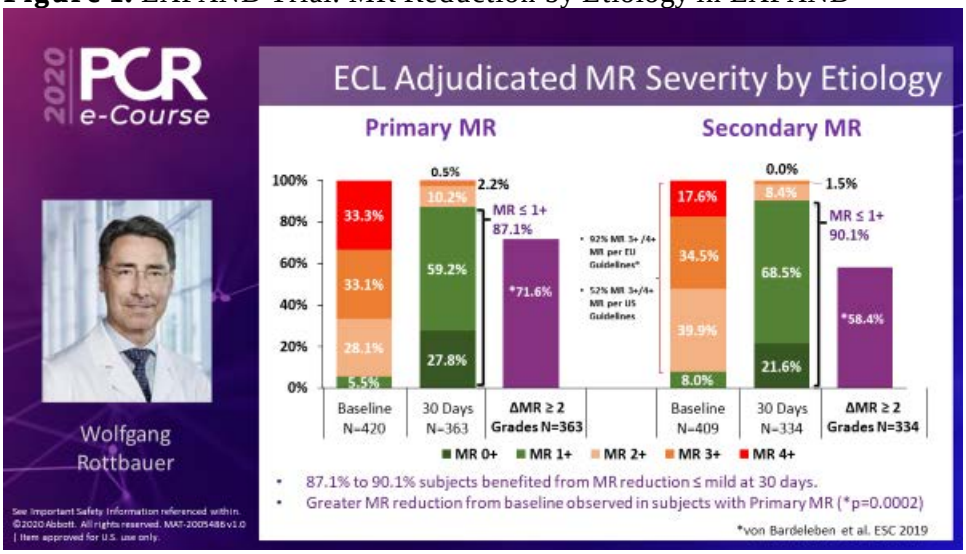
We address each of these in more detail below.

1. Abbott supports coverage for current FDA approved indications for TEER for the treatment of functional MR

Abbott agrees with CMS's assessment that coverage for TEER is reasonable and necessary to treat functional MR according to the current FDA-approved indication for the MitraClip™ therapy. As shown in the COAPT™ trial, functional FMR patients treated with MitraClip™ have reduced mortality, reduced heart failure hospitalizations, and improved quality of life[6].

At the PCR conference in June 2020, results were presented from the EXPAND study, a prospective global study of 1,000+ consecutive MitraClip™ patients[7]. 413 of these patients were confirmed to have functional (secondary) MR by an echo core laboratory. As shown in Figure 1., MR Reduction was substantial for functional MR patients. At baseline, 92.0% of functional MR patients had MR 2+ or greater. After treatment with MitraClip™, 90.1% had MR 1+ or less. Figure 2. shows the significant improvement at 30 days in both functional status (NYHA Class) and health-related quality of life (KCCQ) in functional MR patients.

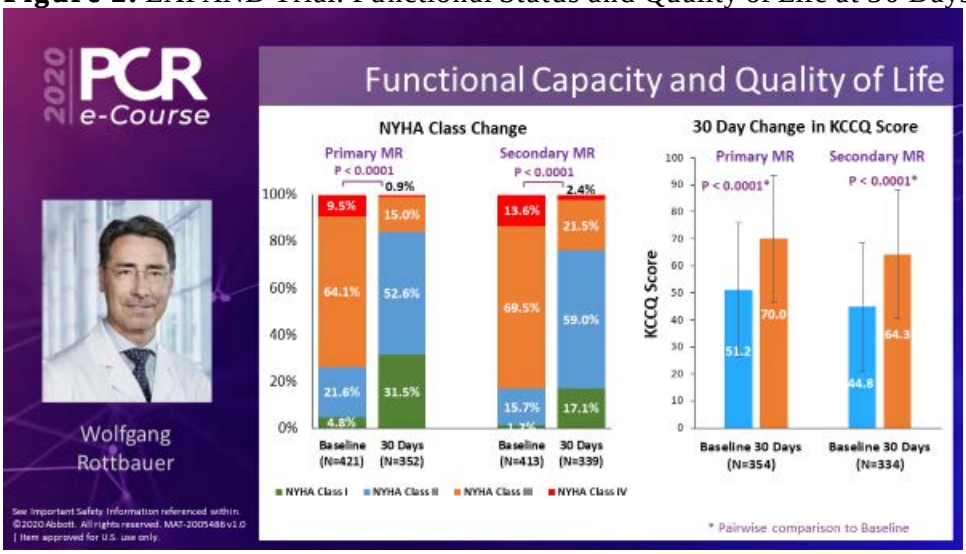
Figure 1. EXPAND Trial: MR Reduction by Etiology in EXPAND



[6] Stone GW, Lindenfeld JA, Abraham WT, et al. Transcatheter mitral-valve repair in patients with heart failure. *N Engl J Med* 2018; 379: 2307-18.

[7] Rottbauer W, Kessler M, Williams M, Mahoney, Ralph Stephan von Bardeleben, Matthew J. Price, Carmelo Grasso, Jose L. Zamorano, Federico M. Asch, Francesco Maisano P, Kar S. Contemporary Clinical Outcomes with MitraClip™ (NTR/XTR) System: Core-lab Echo Results from +1000 Patient the Global EXPAND Study. *2020 PCR e-Course.*

Figure 2. EXPAND Trial: Functional Status and Quality of Life at 30 Days



As shown in the table below, real world 30-day results reported from EXPAND compare favorably with COAPT™ results[8,9].

Table 1. Comparison of 30-Day Results between COAPT™ and EXPAND.

Results in functional MR patients	COAPT™	EXPAND
MR 2+ or greater at baseline	100.0%	92.0%
MR 1+ or less at 30 days	72.9%	90.1%
NYHA Class III-IV at baseline	57.0%	83.7%
NYHA Class I-II at 30 days	76.3%	76.1%
Change in KCCQ Score at 30 days	17.7	19.5

Covering functional MR patients would align CMS policy with numerous private insurers who already cover this population (including large national plans such as Aetna, Humana, and United). This also would remove the situation we have today where functional MR patients effectively lose access to this therapy upon turning 65 years old and becoming eligible for Medicare.

Many of the specific requirements in 1a. and 1b. exist verbatim in the MitraClip™ indication statement. Given that 1c. requires that "mitral valve TEER must be furnished according to an FDA-approved indication," these requirements are redundant and we request they be removed.

The table below shows the proposed NCD requirements that are exactly replicated in the MitraClip™ indication statement.

[8] Stone GW, Lindenfeld JA, Abraham WT, et al. Transcatheter mitral-valve repair in patients with heart failure. *N Engl J Med* 2018; 379: 2307-18.

[9] Arnold SV, Chinnakondepalli KM, Spertus JA, et al. Health Status After Transcatheter Mitral-Valve Repair in Heart Failure and Secondary Mitral Regurgitation: COAPT Trial. *J Am Coll Cardiol*. 2019;73(17):2123-2132.

Table 2. Proposed Requirements Redundant to MitraClip™ Indication

Proposed NCD	MitraClip™ Indication
1.a. …treatment of symptomatic moderate-to-severe or severe functional mitral regurgitation (MR)…	*…treatment of symptomatic, moderate-to-severe or severe secondary (or functional mitral regurgitation (MR)…*
1.b.ii …left ventricular ejection fraction of 20-50%…	*… left ventricular ejection fraction (LVEF) ≥20% and ≤ 50%…*
1.b.iv …left ventricular end-systolic dimension ≤ 70 mm…	*… left ventricular end systolic dimension (LVESD) ≤ 70 mm…*
1a. …remains symptomatic despite stable doses of maximally tolerated guideline-directed medical therapy…	*…MR severity persist despite maximally tolerated GDMT…*

In general, Abbott would like to minimize redundant requirements given that they do not improve patient outcomes and can have unintended consequences related to patient access in the future. As an example, if a TEER device achieves clinical results warranting FDA approval for an expanded indication in the functional MR population (e.g. outside of 20-50% LVEF), those patients would not qualify for coverage until the NCD is re-opened and revised, which can involve a substantial delay. Therefore, we request the following requirements be removed:

1.a. For the treatment of symptomatic moderate-to-severe or severe functional mitral regurgitation (MR) when the patient remains symptomatic despite stable doses of maximally tolerated guideline-directed medical therapy (GDMT).
1.b.ii. Left ventricular ejection fraction of 20-50%
1.b.iv. Left ventricular end-systolic dimension ≤ 70 mm

Another requirement we believe should be removed is *1.b.v. Local heart team had determined that mitral valve surgery will not be offered as a treatment option*.

It is true that to be included in the COAPT™ trial, patients should not have been offered mitral valve surgery. The reason for this statement in the protocol was that mitral valve surgery is not the current standard of care for functional mitral regurgitation. Isolated mitral valve surgery is rarely offered to patients with functional mitral regurgitation. Surgery for secondary MR is only indicated as class of recommendation IIB, level of evidence B in the current ACC/AHA guidelines[10]. In practice, only 4.3% of isolated mitral valve operations were performed on patients with secondary MR[11]. Due to the highly invasive nature of mitral valve surgery, and the lack of evidence associated with mitral valve surgery for the treatment of functional MR, the assumption was that isolated mitral valve surgery is not typically offered to patients with FMR. Application of a restriction that *"mitral valve surgery will not be offered as a treatment option"* to real world practice is not necessary and could cause additional paperwork without patient benefit (e.g. requiring heart team documentation for treatments not offered rather than simply justifying treatment selection).

[10] Nishimura RA, Otto CM, Bonow RO, et al. 2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation* 2017; 135:e1159-e1195

[11] Gammie JS, Chikwe J, et al. Isolated Mitral Valve Surgery: The Society of Thoracic Surgeons Adult Cardiac Surgery Database Analysis. *Ann Thorac Surg* 2018 Sep; 106(3):716-727

In addition, this requirement deviates from the guidance provided in the *2020 Focused Update of the 2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation*[12]. As shown in Figure 9B. of that document, functional MR patients who are on GDMT and have been evaluated / treated with cardiac resynchronization therapy (CRT) yet have persistent symptoms should be evaluated for a transcatheter therapy. If the patient is not a candidate for a transcatheter therapy, or if there is a separate indication for open surgery (e.g. coronary artery bypass graft [CABG]), then the patient is evaluated for mitral valve surgery.

This order of treatment consideration makes sense, given that the COAPT™ trial showed a significant mortality benefit[13] in certain functional MR patients, whereas surgical management of functional MR has been less successful with lack of data supporting either a survival benefit or symptom improvement from surgical FMR correction[14,15]. Despite this, under the proposal, surgical considerations are given undue influence on patient access to TEER, as well as the management of functional MR patients (see Sections 3. and 5. of this comment).

2. Support retaining coverage for degenerative MR at the national level

During the six years of CED for TEER, the mitral module of the TVT Registry has resulted in the generation of meaningful data. Due in part to this registry, Abbott agrees that the concerns CMS expressed back in 2014 in the original decision memo[16] about the generalizability of clinical trial results to the Medicare population have been adequately addressed.

Given the data, we understand why coverage may have been proposed to be managed at the local level. However, we are concerned about the potential for inconsistent local policies and varying access to TEER in the degenerative MR population. In addition, such bifurcated coverage responsibility would be difficult to administer.

If CMS were to retain national coverage for degenerative MR, in the interest of providing streamlined access to patients we recommend a 'coverage to labeling' approach similar to the TAVR NCD 20.32. CMS may wish to consider continuing CED in the degenerative MR population to gather evidence as FDA-approved devices and indications expand in this quickly developing field. This would also avoid having to re-open the NCD any time a new TEER device has a change to its FDA-approved indication.

As a policy covering multiple etiologies could become quite confusing and cumbersome, we propose a distinct and concise section of the policy be focused on the degenerative MR population. Any requirements for degenerative MR should be focused on the clinical delivery of care by the heart team and specific needs of patients. Because functional MR is expected to comprise the majority of MR patients receiving TEER once Medicare coverage is available, we believe that the operator and institutional requirements under the functional MR section of the

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[12] Bonow RO, O'Gara PT, Adams DH, Badhwar V, Bavaria JE, Elmariah S, Hung JW, Lindenfeld J, Morris AA, Satpathy R, Whisenant B, Woo YJ. 2020 focused update of the 2017 ACC expert consensus decision pathway on the management of mitral regurgitation. *J Am Coll Cardiol* 2020;75:2236–70.

[13] Relative risk reduction of 38% in all-cause mortality at 24 months; Stone GW, Lindenfeld JA, Abraham WT, et al. Transcatheter mitral-valve repair in patients with heart failure. *N Engl J Med* 2018; 379: 2307-18.

[14] Gammie JS, Chikwe J, Badhwar V, et al. Isolated Mitral Valve Surgery: The Society of Thoracic Surgeons Adult Cardiac Surgery Database Analysis. Ann Thorac Surg 2018;106:716-27.

[15] Wu AH, et. al. Impact of mitral valve annuloplasty on mortality risk in patients with mitral regurgitation and left ventricular systolic dysfunction. J Am Coll Cardiol 2005;45: 381–7.

[16] Decision Memo for Transcatheter Mitral Valve Repair (TMVR) (CAG-00438N)

NCD would be sufficient to assure the quality of care and that separate requirements are not needed for degenerative MR.

Our proposed language for national coverage for degenerative MR patients is:

B. The Centers for Medicare & Medicaid Services (CMS) covers TEER of the mitral valve for the treatment of degenerative MR under the conditions set forth below.

1. *Treatment of degenerative MR according to an FDA-approved indication and when all of the following conditions are met:*
    a. *Both a cardiothoracic surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease have independently examined the patient and evaluated the patient's suitability for mitral valve surgery and determination of risk; both physicians have documented the rationale for their clinical judgment and the rationale is available to the heart team.*
    b. *The patient (pre-operatively and post-operatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care.*

3. Request modification to certain operator and institutional requirements

Hospital mitral valve procedure requirements

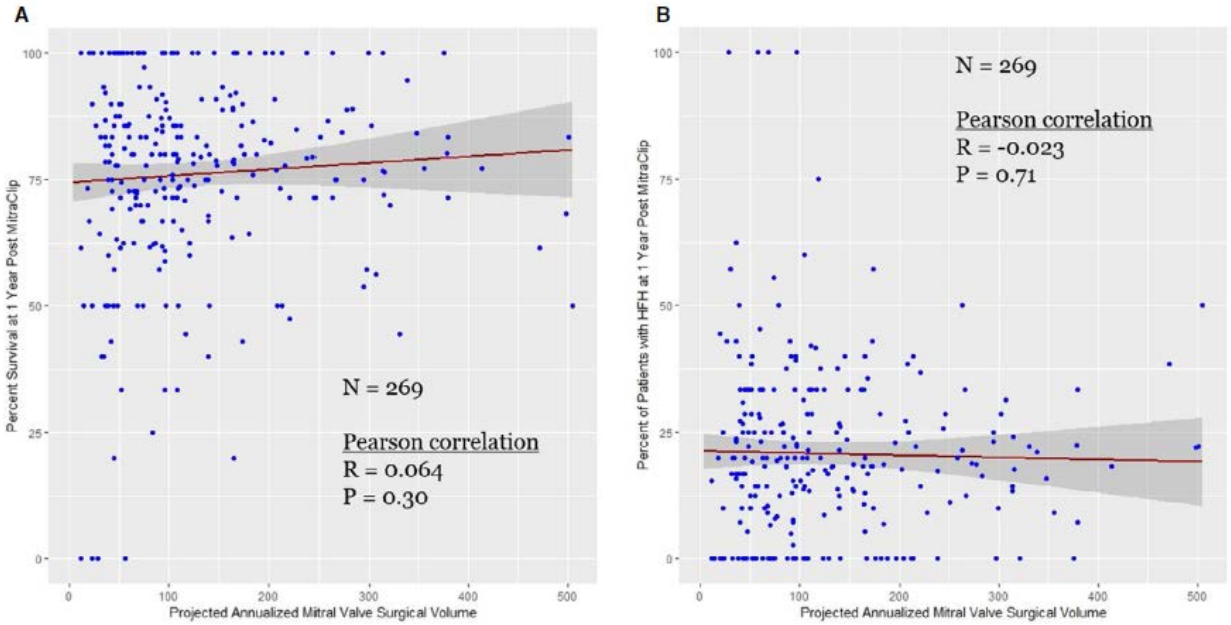
Abbott would like to call attention to two recent publications[17,18] that show no relationship between institutional mitral valve surgical volume and TEER outcomes (see Figures A-B. of Vemulapalli, et al., excerpted below). While the *2019 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Mitral Valve Intervention*[19] recommends substantial mitral valve surgical volume requirements in order to perform TEER, it does not provide any data showing a relationship between the two.

[17] Barker CM, Reardon MJ, Reynolds MR, Feldman TE. Association Between Institutional MV Procedure Volume and MV Repair Outcomes in Medicare Patients *J Am Coll Cardiol Intv*. 11 May 2020. 13(9), 1137-1139

[18] Vemulapalli S, Prillinger J, Thourani V, Yeh RW. Mitral Valve Surgical Volume and Transcatheter Mitral Valve Repair Outcomes: Impact of a Proposed Volume Requirement on Geographic Access *JAHA* May 27, 2020 [Epub ahead of print]

[19] Bonow RO, O'Gara PT, Adams DH, Badhwar V, Bavaria JE, Elmariah S, Hung JW, Lindenfeld J, Morris A, Satpathy R, Whisenant B, Woo YJ. 2019 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Mitral Valve Intervention: A Joint Report of the American Association for Thoracic Surgery, the American College of Cardiology, the Society for Cardiovascular Angiography and Interventions, and The Society of Thoracic Surgeons. *J Am Coll Cardiol* 2020;76:96–117.

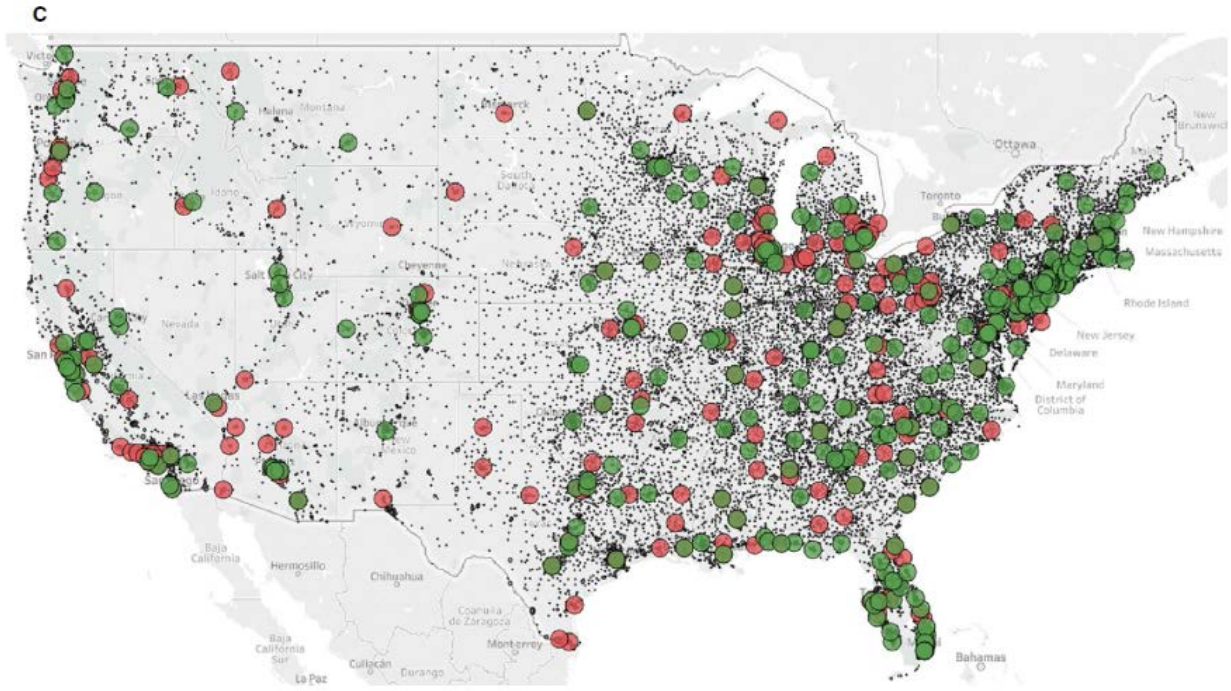
Figure 3: MitraClip™ Outcomes by Institutional Mitral Surgical Volume [Figures A-B. from Vemulapalli et al.]



While institutional and operator requirements are intended to ensure quality care for patients, in the case of mitral valve surgical volumes, the published data do not show a link between the two. The proposed surgical volume requirements would result in patient access restrictions with no apparent patient benefit. This access restriction would primarily impact rural patients (see Figures C-E of Vemulapalli et al.[20]). Figure C is excerpted below showing a map of hospitals with estimated annual mitral valve surgeries of at least twenty (red dots) and at least forty (green dots). It is clear that many "red dot" hospitals could help address geographical access by providing TEER.

[20] Vemulapalli S, Prillinger J, Thourani V, Yeh RW. Mitral Valve Surgical Volume and Transcatheter Mitral Valve Repair Outcomes: Impact of a Proposed Volume Requirement on Geographic Access *JAHA* May 27, 2020 [Epub ahead of print]

Figure 4: Population and Hospitals Stratified by Institutional Mitral Surgical Volume [Figure C. from Vemulapalli et al.]



Black dots represent central points of zip codes with >1000 residents. Green dots represent US hospitals with >40 mitral valve repairs or replacements/year. Red dots represent US hospitals with 20 to 40 mitral valve repairs or replacements/year.

Also noted in Vemulapalli et al. is research showing that drive times of greater than thirty minutes are tied to increased care fragmentation and mortality in TAVR patients[21]. TAVR and TEER are both managed by a heart team and it is not surprising that having a procedure at one institution and follow-up care at a separate institution results in suboptimal outcomes. While long drive times are unavoidable for some rural patients, this relationship supports the need to minimize drive times where possible.

CMS may also be interested in the research showing that patients who are able to travel for non-urgent cardiovascular procedures (such as the majority of TEER) are more likely privately insured[22]. This may indicate that Medicare beneficiaries who would have to travel substantially for access to TEER are more likely to decline the travel and therefore decline the treatment. Geographical access matters for this population, and thresholds for access restriction need to be carefully established by balancing the need for therapy access and clinical outcomes.

Given that there is no evidence that mitral valve surgical procedure volumes are related to TEER outcomes, there is no justification for erecting such a high threshold for new sites. Therefore, Abbott requests the mitral valve surgical volume requirement for hospitals without TEER

[21] Wang A, Li Z, Rymer JA, Kosinski AS, Yerokun B, Cox ML, Gulack BC, Sherwood MW, Lopes RD, Inohara T, et al. Relation of postdischarge care fragmentation and outcomes in transcatheter aortic valve implantation from the STS/ACC TVT Registry. *Am J Cardiol*. 2019;124:912–919.

[22] Langley JD, Johnson TJ, Hohmann SF, Meurer SJ, Garman AN. Empirical analysis of domestic medical travel for elective cardiovascular procedures. *Am J Manag Care*. 2013;19:825–832.

experience be (1) removed entirely or (2) at least reduced to the level currently proposed for hospital programs with mitral valve TEER experience as follows:

Qualifications to begin a mitral valve TEER program for hospitals without mitral valve TEER experience:
The hospital program must have the following:
i. ≥ 20 mitral valve surgeries in the previous year prior to program initiation

Per the above suggestion, Abbott believes that any specific requirement around the proportion of mitral valve surgical repairs should be removed.

While we understand the inclusion of a transcatheter procedure maintenance volume in the *2019 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Mitral Valve Intervention* and in the proposed NCD, we are concerned about both a lack of clarity in the coverage requirement as written and also any unintended consequences.

First, Abbott proposes one clarification to this requirement:

i. ≥ 20 transcatheter mitral valve interverventions [sic] *per year or ≥ 40 interventions every two years*

To align with the clarified scope of the NCD, this requirement should read:

i. ≥ 20 mitral valve TEER per year or ≥ 40 every two years

However, our concerns are that this requirement, when coupled with an annual open mitral valve surgical volume requirement may have unintended consequences. Specifically, by having two separate and distinct volume requirements, sites may be improperly pressured into offering one treatment or the other to a patient in order to remain eligible for Medicare coverage. It is hard to predict how transcatheter interventions will develop over the next five or ten years.

Abbott is conducting a trial comparing MitraClip™ to open mitral valve surgery among intermediate risk patients. While a few years away, results from this trial (or others) could potentially impact the distribution of patients receiving open or transcatheter interventions.

Therefore, if CMS elects to retain a mitral valve surgical volume requirement, Abbott requests that CMS follow the precedent in the TAVR NCD 20.32 by creating a blended procedural volume requirement for sites with mitral valve TEER experience. This would allow the TEER NCD to be flexible enough in a rapidly developing space while still requiring institutions to treat a minimum number of patients with mitral valve disease. Our suggestion is to revise the language as follows:

Qualifications for hospital programs with mitral valve TEER experience:
The hospital program must maintain the following:
i. ≥ 20 transcatheter mitral valve interverventions [sic] per year or ≥ 40 interventions every two years; and
ii. ≥ 20 mitral valve surgeries per year or ≥ 40 every two years; and

To a combined single volume requirement:

Qualifications for hospital programs with mitral valve TEER experience:
The hospital program must maintain the following:
i. ≥ 40 mitral valve interventions (mitral valve surgery or TEER) per year or ≥ 80 interventions every two years

Cardiac surgeon procedure volume requirements

While the two recent publications cited above focused on institutional volumes, it is also important to consider the new proposed requirement for individual cardiac surgeons. If there is no link between mitral valve surgical volumes and TEER outcomes at the institutional level, there is no reason to believe a link would exist at the surgeon level. Conceptually, it also does not make sense that volumes for one physician and procedure would result in better outcomes for a different procedure that requires a different skill set and is often performed by a different physician.

We would also like to note that the original TMVR NCD 20.33 did not include a volume requirement for the cardiac surgeon on the heart team. We are aware of no data indicating that adding such a requirement is necessary or could reasonably be expected to improve TEER patient outcomes.

Abbott requests that the proposed procedural volume requirements for the cardiac surgeon on the heart team be removed. If not removed, the required volume should be lowered commensurate with a lower hospital volume requirement (See Appendix A).

Physician board eligibility and certification requirements

Abbott also requests the removal of board eligibility or certification requirements for the cardiac surgeon, interventional cardiologist, and echocardiographer. These requirements are not included in the TAVR NCD 20.32, and it is unclear why they are included here. If it is deemed vital to retain the board eligibility or certification requirements, we request that the allowance for foreign equivalents be added as in the original NCD 20.33.

4. Support the addition of a heart failure physician specialist as a required member of the heart team

Abbott agrees with and supports the proposed requirement for a "heart failure physician specialist experienced in the care and treatment of mitral valve disease" on the heart team. The heart failure physician has a clear and integral role in the treatment of functional MR patients,

as noted in the *2020 Focused Update of the 2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation*[23].

5. Request modification of required face-to-face evaluations for every functional MR patient

CMS proposes to require a face-to-face consult with the interventional cardiologist and the cardiac surgeon for all functional MR patients. Abbott believes the NCD requirements should align with the *2020 Focused Update of the 2017 ACC Expert Consensus Decision Pathway on the Management of Mitral Regurgitation*[24], which outlines evaluation by the interventional cardiologist and the heart failure physician.

As noted in the consensus document, the heart team may determine that face-to-face evaluation by the cardiac surgeon is necessary for certain patients, such as those requiring another open cardiac procedure (e.g., CABG).

Abbott would also like CMS to consider the requirement for two face-to-face evaluations for functional MR patients more generally. While CMS is waiving the face-to-face requirement during the COVID-19 Public Health Emergency, that flexibility is expected to expire. Local conditions may result in sustained COVID-19 (or other) risks that require limited face-to-face interaction – for public health or individual patient reasons. As the requirements in this NCD will be rigid and fixed until the NCD is formally reconsidered again, Abbott suggests that CMS strike the specificity of "independently examined the patient face-to-face" and allow the local heart teams to determine the most appropriate way to evaluate patients given individual and local circumstances at the time.

Taking into account both the specialty considerations and flexibility on face-to-face evaluations, Abbott requests the following modification:

1.c.iv The heart team interventional cardiologist and heart failure physician have:

1. *Examined the patient, evaluated the patient's suitability for TEER or other treatment pathways; and*
2. *Documented and made available to the other heart team members the rationale for their clinical judgment.*

6. Request modification or removal of the exclusion for patients with coexisting conditions

Abbott is very concerned about the patient access impact of the proposed extensive list of coexisting conditions that would result in TEER not being covered in specific cases. While the COAPT™ trial excluded some of these patients, converting these to coverage exclusions fails to

[23] Bonow RO, O'Gara PT, Adams DH, Badhwar V, Bavaria JE, Elmariah S, Hung JW, Lindenfeld J, Morris AA, Satpathy R, Whisenant B, Woo YJ. 2020 focused update of the 2017 ACC expert consensus decision pathway on the management of mitral regurgitation. *J Am Coll Cardiol* 2020;75:2236–70.

[24] Bonow RO, O'Gara PT, Adams DH, Badhwar V, Bavaria JE, Elmariah S, Hung JW, Lindenfeld J, Morris AA, Satpathy R, Whisenant B, Woo YJ. 2020 focused update of the 2017 ACC expert consensus decision pathway on the management of mitral regurgitation. *J Am Coll Cardiol* 2020;75:2236–70.

take into account real-world impacts to patients who may benefit from TEER, as judged by their local heart team. It also ignores that exclusion criteria are often included in clinical trials to attempt to isolate the effect of the treatment being studied, not because those patients are not expected to benefit. Excluding patients with certain coexisting conditions helps lower the trial population by eliminating "noise" in the clinical outcomes results, thereby lowering the total number of patients that need to receive a not-yet-proven therapy. This is done to meet an ethical maxim of all clinical research: the number of patients exposed to the risks associated with an unapproved device should be the minimum number statistically required, and no more.

None of the items on the exclusions list are listed as a Contraindication in the MitraClip™ IFU[25]. Only one is listed in the *Warnings* section, specifically:

- *Use caution when treating patients with hemodynamic instability requiring inotropic support or mechanical heart assistance due to the increased risk of mortality in this patient population. The safety and effectiveness of MitraClip™ in these patients has not been evaluated.*

Hemodynamic Instability

Despite the warning statement on treating patients with hemodynamic instability, there are numerous case studies[26], case series[27,28,29], and an analysis presented at PCR in June 2020[30] that evaluate the use of MitraClip™ in patients with cardiogenic shock, who are often on inotropic support and/or mechanical heart assistance. Removing coverage for these patients will limit access for a very sick patient population that has been shown to benefit from TEER. Abbott agrees that more research is needed regarding the use of MitraClip™ in patients with cardiogenic shock. However, the proposed NCD language immediately forestalls such use among these extremely vulnerable patients.

Coexisting Valve Disease

Another specific item of concern for noncoverage is *i. Coexisting aortic or tricuspid valve disease requiring surgery or transcatheter intervention.* First, it is not uncommon for functional MR patients undergoing MitraClip™ to have 3+ or 4+ tricuspid regurgitation (TR)[31], since the two diseases are interdependent. Many times, severe TR is due to the increased right

[25] MitraClip™ NTR/XTR Clip Delivery System, Instructions for Use (March 2019).

[26] Alkhouli M, Wolfe S, Alqahtani F, et al. The Feasibility of Transcatheter Edge-to-Edge Repair in the Management of Acute Severe Ischemic Mitral Regurgitation. *JACC Cardiovasc Interv*. 2017;10(5):529-531.

[27] Seizer P, Schibilsky D, Sauter R, et al. Percutaneous Mitral Valve Edge-to-Edge Repair Assisted by Hemodynamic Support Devices: A Case Series of Bailout Procedures. *Circ Heart Fail*. 2017;10(5):e004051.

[28] Garcia S, Alsidawi S, Bae R, et al. Percutaneous Mitral Valve Repair With MitraClip in Inoperable Patients With Severe Mitral Regurgitation Complicated by Cardiogenic Shock. *J Invasive Cardiol*. 2020;32(6):228-231.

[29] Dawkins S, Cheng R, Tso J, Makar M, Hamilton M, Makkar R, Kar S. 600.52 What Is the Impact of Percutaneous Mitral Valve Repair on Inotrope Use in Cardiogenic Shock? *J Am Coll Cardiol Intv*. 2019 Feb, 12 (4 Supplement) S55-S56.

[30] Estevez-Loureiro R, Psotka MA, Yu Y, Prillinger J, Tang GHL. Percutaneous Edge-to-Edge Mitral Valve Repair in Patients Hospitalized with Cardiogenic Shock: A United States Nationwide Analysis. *2020 PCR e-Course.*

[31] Per the EXAND study, 19.6% of functional / secondary MR patients had 3+ or 4+ TR. Rottbauer W, Kessler M, Williams M, Mahoney, Ralph Stephan von Bardeleben, Matthew J. Price, Carmelo Grasso, Jose L. Zamorano, Federico M. Asch, Francesco Maisano P, Kar S. Contemporary Clinical Outcomes with MitraClip™ (NTR/XTR) System: Core-lab Echo Results from +1000 Patient the Global EXPAND Study. *2020 PCR e-Course.*

ventricular afterload due to severe MR. If concomitant tricuspid disease is excluded from coverage, these patients will be left with no transcatheter option for MR treatment, and indirectly, even tricuspid treatment. This is primarily because current trials for the evaluation of tricuspid valve regurgitation rely on the mitral regurgitation to be corrected first, prior to the patients being eligible for the trials evaluating TR. For example, Abbott is currently conducting an IDE study (TRLIMUNATE Pivotal, approved for coverage by CMS in 2019) focused on transcatheter tricuspid valve repair[32]. While the study is focused on isolated TR, patients with combined MR and TR can be enrolled in the trial after their MR is treated. Such patients are re-evaluated after MitraClip™ implantation to determine if they continue to qualify for trial participation. This is a two-step process: 1) treat MR, and then 2) re-evaluate for TR. In some patients, TR improves after treatment of the MR in some patients[33,34]. Allowing treatment of the MR first, prevents patients from undergoing a second procedure, particularly those whose TR resolves after MR treatment. Only patients with residual severe TR post MR correction are eligible for the TRILUMINATE Pivotal trial.

Abbott is concerned that if finalized as proposed, patients with combined MR and TR may be "locked out" of any treatment option. These patients cannot enroll in a trial to potentially treat their TR without treating their MR first, especially if such patients are excluded by the NCD.

COPD

A third specific concern on the exclusion list is *ii. COPD requiring continuous home oxygen therapy or chronic outpatient oral steroid use.* A presence of baseline COPD is reported in up to 45% of patients seeking MR treatment[35], and 14.2% of TEER cases in the TVT registry had oxygen-dependent lung disease[36]. In patients with COPD and heart failure, there is a combined deleterious effect on respiratory function such that home oxygen is often required at much less severe degrees of COPD (i.e., primary resp dysfunction) than in patients with isolated COPD absent heart failure.

Open surgical correction of MR in these patients is associated with an increase in postoperative adverse outcomes of pulmonary complications, infectious complications and death[37]. Given the high-risk status of these patients, it has been shown that just making the valvular surgery less invasive can bring significant reduction in morbidity and resource utilization when compared with a median sternotomy surgical approach. The minimally invasive surgery studied in Santana, et al. still tends to have a longer aortic cross clamp and cardiopulmonary bypass times which can potentially negatively impact the outcomes. A transcatheter approach is expected to further minimize the procedural trauma to these patients and improve outcomes.

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[32] NCT03904147

[33] Rajbanshi BG, Suri RM, Nkomo VT, et al. Influence of mitral valve repair versus replacement on the development of late functional tricuspid regurgitation. *J Thorac Cardiovasc Surg*. 2014;148(5):1957-1962.

[34] Yilmaz O, Suri RM, Dearani JA, et al. Functional tricuspid regurgitation at the time of mitral valve repair for degenerative leaflet prolapse: the case for a selective approach. *J Thorac Cardiovasc Surg*. 2011;142(3):608-613.

[35] Giannini C, D'ascenzo F, Fiorelli F, et al. A meta-analysis of MitraClip combined with medical therapy vs. medical therapy alone for treatment of mitral regurgitation in heart failure patients. *ESC Heart Fail*. 2018;5(6):1150-1158.

[36] Sorajja P, Vemulapalli S, Feldman T, et al. Outcomes With Transcatheter Mitral Valve Repair in the United States: An STS/ACC TVT Registry Report. *J Am Coll Cardiol*. 2017;70(19):2315-2327.

[37] Santana O, Reyna J, Benjo AM, Lamas GA, Lamelas J. Outcomes of minimally invasive valve surgery in patients with chronic obstructive pulmonary disease. *Eur J Cardiothorac Surg*. 2012;42(4):648-652.

Therefore, a safer and less invasive MitraClip™ procedure is a superior alternative compared to both surgical or medical treatment for MR patients with COPD. Local heart teams should make the determination if a patient's COPD or chronic treatment is expected to overly interfere with expected benefits from TEER. Not allowing coverage for any in this high-risk patient population would result in patients not receiving a treatment that they are expected to strongly benefit from.

Advanced Heart Failure / Planned Heart Transplant Surgery

Yet another exclusion proposed is patients with stage D heart failure or those with planned cardiac surgery within the next 12 months. This is another patient group that has been studied with promising early results. In the "MitraBridge" study[38] presented at PCR in 2019, patients with advanced heart failure at various stages of the evaluation for a heart transplant received MitraClip™. This global study evaluated 98 patients with advanced/end stage heart failure and concluded that MitraClip™ as a bridge-to-transplant strategy was safe and effective with 25% of studied patients receiving a heart transplant, 15% of patients remaining/becoming eligible for a heart transplant, and 23% of patients "delisted" due to clinical improvements. While exploratory in nature, these early results show that reduction in MR due to the TEER procedure can impact outcomes for certain patients with advanced heart failure. Local heart teams should evaluate patient-specific circumstances when considering TEER, including stage of heart failure, MR severity, and potentially heart transplant considerations. While early intervention is preferred, some patients may not be evaluated by a heart team until their heart failure is advanced / end stage. Such a delay in seeking care should not result in blanket non-coverage if the local heart team believes the patient will benefit from TEER.

Role of the Heart Team and Requested Revision

It is also worth noting that the proposed requirement below is sufficient to ensure patients treated with TEER are, in the expert opinion of their local heart team, expected to benefit from the therapy.

TEER of the mitral valve for the treatment of functional MR is not covered for patients in whom existing co-morbidities would preclude the expected benefit from correction of the mitral valve.

The site heart team should be able to offer TEER to patients who may be have comorbidities included on the COAPT trial exclusions list, based on their clinical judgment of the benefit-risk associated with TEER.

[38] Godino C, Estévez-Loureiro R, Portolés Hernández A, Arzamendi D, Peregrina Fernández E, Taramasso M, Fam N.P, Ho E. C, Asgar A, Vitrella G, Margonato A, Ooms JF, Tamburino C, Tarantini G, Petronio A.S, Grasso C, Maisano F, Colombo A, Van Mieghem N.M, Montorfano M, Curello S, Crimi G and Saia F on behalf of MitraBridge Investigators. The "MitraBridge" international study: MitraClip procedure as "bridge therapy" for heart transplantation. *2019 PCR E-course.*

While Abbott would prefer the entire section excluding coexisting conditions be removed, we urge CMS to consider our comment and remove these exclusions from the final decision:

i. Coexisting aortic or tricuspid valve disease requiring surgery or transcatheter intervention
ii. COPD requiring continuous home oxygen therapy or chronic outpatient oral steroid use
iii. ACC / AHA stage D heart failure
v. Hemodynamic instability requiring inotropic support or mechanical heart assistance
vii. … any planned cardiac surgery within the next 12 months

As we discuss in greater detail in Section 8 below, we support use of CED as a mechanism to extend coverage for these currently-excluded conditions.

7. Support the scope clarification to TEER

Abbott agrees that coverage should be limited to clinically proven technologies / mechanisms of action (e.g. edge-to-edge repair such as MitraClip™).

Abbott does not believe that other mechanisms of action to treat degenerative or functional MR should be included in NCD 20.33 at this time, given the paucity of data for these transcatheter interventions (e.g. annuloplasty, chordae tendineae repair) and lack of any FDA-approved devices. Under this proposal, as new mechanisms of action demonstrate their clinical efficacy and gain FDA approval, they could be incorporated into NCD 20.33, evaluated under a new NCD, or deferred to the MACs to manage coverage locally. This is an appropriate way to manage a developing and ever-changing clinical area.

8. Support CED and mandatory registry participation to provide access for patients with coexisting conditions excluded in the proposal

Abbott believes the TVT Registry has been and continues to be an important repository of data. As a result, we support continuation of CED and mandatory TVT Registry participation, permitting Medicare coverage for functional MR patients with coexisting conditions currently excluded by the proposal (e.g., tricuspid and / or aortic disease requiring intervention, hemodynamic instability, advanced HF, COPD, etc.). Abbott supports this approach as it provides coverage for patients while additional evidence is developed through the registry.

If CMS chooses to reinstate CED, Abbott requests that the CED requirements be limited to participation in a CMS approved national registry, eliminating trial design and endpoint-specific requirements for IDE trials contained in the current NCD.

Independent of coverage conditions and requirements, Abbott remains committed to continued evidence development in the transcatheter mitral valve space. We were encouraged to see CMS support for the use of real-world evidence in the future.

Conclusion

Given the life-saving benefit of the MitraClip™ therapy, we urge CMS to move as quickly as possible to finalize Medicare coverage for TEER for functional MR patients.

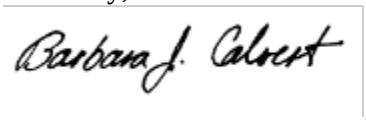
In addition, we support the following revisions to the proposed coverage decision:

- Remove overly restrictive exclusions for coexisting conditions, particularly those related to hemodynamic instability, tricuspid valve disease, and COPD
- Retain CED as a mechanism to provide coverage for patients excluded in the proposal while evidence is developed using the mitral module of the TVT Registry
- Remove / revise mitral valve surgery volume requirements for both hospital programs and cardiac surgeons
- Remove required in-person surgical consult for every function MR patient (may be conducted as needed per local heart team)
- Modify separate open surgical and transcatheter mitral valve requirements into a single, blended procedural volume requirement, as separate volume requirements may have unintended consequences, particularly as the transcatheter space develops
- Include coverage for degenerative MR patients at the national level to ensure consistent access for patients
- Remove coverage requirements that are included in the MitraClip™ FDA indication for functional MR patients
- Remove all board eligibility or certification requirements to better align with TAVR NCD 20.32

Please refer to Appendix A. to see a detailed summary of changes requested.

Thank you for considering our comments. Please let us know if you have any questions or require additional information.

Sincerely,



Barbara J. Calvert
Director, Medical Products, Reimbursement
Abbott

Appendix A: List of Suggested Edits to Proposed Decision Memo for Transcatheter Mitral Valve Repair (TMVR) (CAG-00438R)

Proposed Decision Memo	Abbott Change Request
1. TEER of the mitral valve is covered as follows: *a. For the treatment of symptomatic moderate-to-severe or severe functional mitral regurgitation (MR) when the patient remains symptomatic despite stable doses of maximally tolerated guideline-directed medical therapy (GDMT).* *b. Eligible patients must also meet the following criteria:* *i. Ischemic or non-ischemic cardiomyopathy; and* *ii. Left ventricular ejection fraction of 20-50%; and* *iii. New York Heart Association Functional Class II, III, or IVa (ambulatory); and* *iv. Left ventricular end-systolic dimension ≤ 70 mm; and* *v. Local heart team has determined that mitral valve surgery will not be offered as a treatment option.*	*1. TEER of the mitral valve is covered as follows:* *a. For the treatment functional mitral regurgitation (MR) according to an FDA-approved indication.* *b. Eligible patients must also meet the following criteria:* *i. Ischemic or non-ischemic cardiomyopathy; and* *ii. New York Heart Association Functional Class II, III, or IVa (ambulatory); and*
1. TEER of the mitral valve is covered as follows: *c. The mitral valve TEER must be furnished according to an FDA-approved indication and meet the following conditions:* *…* *iv. The heart team cardiac surgeon and interventional cardiologist have:* *1. Independently examined the patient face-to-face, evaluated the patient's suitability for surgical mitral valve repair, TEER, maximally tolerated GDMT, or palliative therapy; and* *2. Documented and made available to the other heart team members the rationale for their clinical judgment.*	*1. TEER of the mitral valve is covered as follows:* *c. The mitral valve TEER must be furnished according to an FDA-approved indication and meet the following conditions:* *…* *iv. The heart team interventional cardiologist and heart failure physician have:* *1. Examined the patient, evaluated the patient's suitability for TEER or other treatment pathways; and* *2. Documented and made available to the other heart team members the rationale for their clinical judgment*

Proposed Decision Memo	Abbott Change Request
Qualifications to begin a mitral valve TEER program for hospitals without mitral valve TEER experience: *The hospital program must have the following:* *i. ≥ 40 mitral valve surgeries in the previous year prior to program initiation, at least 20 of which are mitral valve repairs; and* *ii. …*	***Proposal 1:*** *Qualifications to begin a mitral valve TEER program for hospitals without mitral valve TEER experience:* *The hospital program must have the following:* *~~i. ≥ 40 mitral valve surgeries in the previous year prior to program initiation, at least 20 of which are mitral valve repairs; and~~* *ii. …* ***Proposal 2:*** *Qualifications to begin a mitral valve TEER program for hospitals without mitral valve TEER experience:* *The hospital program must have the following:* *i. ≥ 20 mitral valve surgeries in the previous year prior to program initiation; and* *ii. …*

Proposed Decision Memo	Abbott Change Request
The heart team must include: *i. Cardiac surgeon:* *a. With ≥ 20 mitral valve surgeries in the previous year or ≥ 40 in the 2 years prior to program initiation, 50% of which are mitral valve repairs; and* *b. Who is board eligible or certified in cardiothoracic surgery; and* *ii. Interventional cardiologist:* *a. With professional experience of ≥ 100 career structural heart disease procedures; or ≥ 30 left-sided structural procedures per year; and* *b. With participation in ≥ 20 career trans-septal interventions including 10 as primary or co-primary operator; and* *c. Who is board eligible or certified in interventional cardiology; and* *iii. Interventional echocardiographer:* *a. With professional experience of ≥ 10 trans-septal guidance procedures and ≥ 30 structural heart procedures; and* *b. Who is board eligible or certified in transthoracic and transesophageal echocardiography with advanced training per the American Society of Echocardiography standards; and* *iv.…*	***Proposal 1:*** *The heart team must include:* *i. Cardiac surgeon with mitral valve surgical experience; and* *ii. Interventional cardiologist:* *a. With professional experience of ≥ 100 career structural heart disease procedures; or ≥ 30 left-sided structural procedures per year; and* *b. With participation in ≥ 20 career trans-septal interventions including 10 as primary or co-primary operator; and* *iii. Interventional echocardiographer:* *a. With professional experience of ≥ 10 trans-septal guidance procedures and ≥ 30 structural heart procedures; and* *iv.…* ***Proposal 2:*** *The heart team must include:* *i. Cardiac surgeon:* *a. With ≥ 10 mitral valve surgeries in the previous year or ≥ 20 in the 2 years prior to program initiation* *ii. Interventional cardiologist:* *a. With professional experience of ≥ 100 career structural heart disease procedures; or ≥ 30 left-sided structural procedures per year; and* *b. With participation in ≥ 20 career trans-septal interventions including 10 as primary or co-primary operator; and* *iii. Interventional echocardiographer:* *a. With professional experience of ≥ 10 trans-septal guidance procedures and ≥ 30 structural heart procedures; and* *iv.…* ***Alternate wording for board certification requirements:*** *Who is board eligible or certified in [specialty] or similar foreign equivalent*

Proposed Decision Memo	Abbott Change Request
Qualifications for hospital programs with mitral valve TEER experience: *The hospital program must maintain the following:* *i. ≥ 20 transcatheter mitral valve interverventions per year or ≥ 40 interventions every two years; and* *ii. ≥ 20 mitral valve surgeries per year of ≥ 40 every two years; and* *iii. …*	*Qualifications for hospital programs with mitral valve TEER experience:* *The hospital program must maintain the following:* *i. ≥ 40 mitral valve interventions (mitral valve surgery or TEER) per year or ≥ 80 interventions every two years* ii. …

Proposed Decision Memo	Abbott Change Request
TEER of the mitral valve for the treatment of functional MR is not covered for patients with any of the following conditions: *i. Coexisting aortic or tricuspid valve disease requiring surgery or transcatheter intervention; or* *ii. COPD requiring continuous home oxygen therapy or chronic outpatient oral steroid use; or* *iii. ACC / AHA stage D heart failure; or* *iv. Estimated pulmonary artery systolic pressure (PASP) > 70 mmHg as assessed by echocardiography or right heart catheterization, unless active vasodilator therapy in the catheterization laboratory is able to reduce the pulmonary vascular resistance (PVR) to < 3 Wood Units or between 3 and 4.5 Wood Units with a v wave less than twice the mean of the pulmonary capillary wedge pressure (PCWP); or* *v. Hemodynamic instability requiring inotropic support or mechanical heart assistance; or* *vi. Physical evidence of right-sided congestive heart failure with echocardiographic evidence of moderate or severe right ventricular dysfunction; or* *vii. Need for emergent or urgent surgery for any reason or any planned cardiac surgery within the next 12 months.* *TEER of the mitral valve for the treatment of functional MR is not covered for patients in whom existing comorbidities would preclude the expected benefit from correction of the mitral valve.*	*TEER of the mitral valve for the treatment of functional MR is not covered for patients in whom existing comorbidities would preclude the expected benefit from correction of the mitral valve.*

Proposed Decision Memo	Abbott Change Request
[No CED requirements]	*The heart team and hospital are participating in a prospective, national, audited registry that: 1) consecutively enrolls TEER patients; 2) accepts all manufactured devices; 3) follows the patient for at least one year; and, 4) complies with relevant regulations relating to protecting human research subjects, including 45 Code of Federal Regulations (CFR) Part 46 and 21 CFR Parts 50 & 56. The following outcomes must be tracked by the registry; and the registry must be designed to permit identification and analysis of patient, practitioner, and facility level variables that predict each of these outcomes:* *i. Stroke;* *ii. All-cause mortality;* *iii. Transient Ischemic Attacks (TIAs);* *iv. Major vascular events;* *v. Acute kidney injury;* *vi. Repeat mitral valve procedures;* *vii. Quality of Life (QoL).* *The registry shall collect all data necessary and have a written executable analysis plan in place to address the following questions (to appropriately address some questions, Medicare claims or other outside data may be necessary):* *i. How do outcomes and adverse events compare to the pivotal clinical studies?* *ii. What is the long-term durability of the device?* *iii. What are the long-term outcomes and adverse events?* *iv. What coexisting conditions contribute to outcomes (e.g., combined valve disease, hemodynamic instability, COPD, stage D heart failure)?* *v. What morbidity and procedure-related factors contribute to outcomes?* *Consistent with section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality supports clinical research studies that CMS determines meet the above-listed standards and address the research questions.*

Proposed Decision Memo	Abbott Change Request
[No CED requirements]	*TEER for functional MR uses that are not expressly listed as an FDA-approved indication when performed within an FDA-approved trial.*
B. CMS proposes to revise current national coverage determination (NCD) 20.33 with respect to patients with degenerative MR. CMS is proposing that coverage determinations under section 1862(a)(1)(A) of the Act for on-labeled uses of FDA approved devices for these patients will be made by Medicare Administrative Contractors (MACs).	*B. The Centers for Medicare & Medicaid Services (CMS) covers TEER of the mitral valve for the treatment of degenerative MR under the conditions set forth below.* *1. Treatment of degenerative MR according to an FDA-approved indication and when all of the following conditions are met:* *a. Both a cardiothoracic surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease have independently examined the patient and evaluated the patient's suitability for mitral valve surgery and determination of risk; both physicians have documented the rationale for their clinical judgment and the rationale is available to the heart team.* *b. The patient (pre-operatively and post-operatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care.*