



HEART VALVE DISEASE POLICY TASK FORCE

CMS NATIONAL COVERAGE DETERMINATION FOR TAVR

On June 27th, 2018 the Centers for Medicare and Medicaid Services (CMS) announced that they are reconsidering the National Coverage Determination (NCD) for transcatheter aortic valve replacement (TAVR). TAVR is a minimally invasive alternative to open heart surgery for many patients who need a new heart valve. The new NCD determination could impact patient access to TAVR—potentially widening or limiting the ability of patients to get TAVR.

Below are answers to some frequently asked questions about the NCD process and the issues being considered.

What is a National Coverage Determination (NCD)?

Medicare reimburses—or pays for—medical items and services that are considered “reasonable and necessary.” A national coverage determination (NCD) is a nationwide policy on whether Medicare will pay for a particular item or service, and under what circumstances.

What is Coverage with Evidence Development (CED)?

As part of a NCD, CMS may require coverage with evidence development (CED). A CED requires that as a condition of coverage, additional data must be collected so that CMS can learn more about clinical outcomes, effectiveness, and appropriateness of the item or service being considered.

What is a National Coverage Analysis (NCA)?

This is the process that CMS conducts that leads to the publication of a National Coverage Determination (NCD). The NCA compiles all public comments and is particularly focused on scientific evidence. Once CMS issues the NCD, it becomes the final policy on reimbursement for an item or service.

What is the current TAVR NCD?

In May 2012, CMS issued a National Coverage Determination (NCD) covering transcatheter aortic valve replacement (TAVR) under Coverage with Evidence Development (CED). As part of the NCD,

medical providers must meet certain requirements before they may perform TAVR to treat symptomatic aortic stenosis according to an FDA-approved indication. The CED requires mandatory entry of all TAVR patients into a qualified national registry. Additionally, all TAVR patients must have face-to-face exams with two cardiac surgeons and be under the care of a heart team. Both surgeons must agree that the patient qualifies for TAVR. Additionally, criteria for establishing and maintaining TAVR programs are laid out in the NCD and include a minimum number of annual surgical and interventional cardiac procedures.

Has the TAVR NCD reconsideration process been officially opened?

Yes. On Wednesday, June 27th, 2018 CMS [reopened for reconsideration the NCD for TAVR](#).

Why is it important that the TAVR NCD has been officially opened?

Reopening the NCD means CMS is reexamining how TAVR will be covered and reimbursed moving forward. The new determination could impact patient access to TAVR—potentially widening or limiting the ability of patients to get TAVR.

Why was the NCD reopened for reconsideration?

Patient advocates have expressed concern that the current NCD requirements, in particular procedural requirements that tie the ability to perform TAVR to the volume of surgical and interventional cardiac procedures performed, have negatively impacted access to TAVR. The NCD was triggered by three California physicians who formally requested reconsideration of the NCD in a [letter](#) dated October 25th, 2017. The letter states that, *“now that the procedure is streamlined, with excellent outcomes, CMS approval and reimbursement should be based on quality and not non-TAVR procedure volume surrogates for quality. Therefore, [CMS should either] . . . 1) Retire the NCD; or 2) remove the volume criteria from the NCD.”*

Will CMS focus the reconsideration only on what was stated in the letter?

During the reconsideration process, CMS has the opportunity to evaluate all aspects of the existing TAVR NCD.

What is the current timeline of the NCD reconsideration?

The NCD was reopened on June 27th, 2018 for reconsideration with an initial 30-day comment period ending on July 27th, 2018. The Draft NCD will be published no later than March 27th, 2019. This will be followed by an additional 30-day comment period. The Final NCD will be published no later than June 25th, 2019.

What could the impact or outcome of the NCD reopening be?

The NCD reopening will result in revision of the current policy. Changes to the NCD policy will influence hospitals’ ability to open or maintain TAVR programs.



What concerns have been raised about this NCD by the patient, provider, and heart center communities?

Many of these constituents feel that the current NCD restricts patient access and creates inequalities. Untreated heart valve disease is fatal and currently undertreated. The NCD—especially with the procedural volume requirements—creates barriers to a less-invasive, often patient-preferred treatment that has been proven to be a safe and effective option for treating aortic stenosis in inoperable, high-risk, and intermediate-risk patients. This restricted access creates inequalities since depending on which hospital a patient visits and which doctor they see, patients can have vastly different experiences. Many in these communities are concerned that any increase in procedural volume requirements could close TAVR facilities and prevent the opening of new ones—and that the subsequent harm outweighs any potential benefit.

What changes to the NCD would the Heart Valve Disease Policy Task Force Support?

The [Task Force](#) believes that all patients should have access to all appropriate treatments. Volume is no longer a necessary surrogate for outcomes and there should be more emphasis on timely intervention and quality outcomes. The current 4 health outcomes that the NCD measures (mortality, stroke, vascular complications, and bleeding) are medical. The NCD should also take into consideration other important outcomes that matter to patients including: quality of life, mobility, length of stay, new onset of AFib, staying out of the hospital, and location of discharge. The Task Force also believes that the requirement for two surgeons to approve TAVR creates unnecessary roadblocks and delays for patients. The process should instead formally incorporate a shared decision-making process where patients are free to obtain opinions and recommendations from a range of experts. Additionally, patients should have free or reduced-cost access to the Transcatheter Valve Therapy (TVT) Registry data and meaningful information on hospital performance.

What is the MEDCAC and how is it connected to the NCD?

The Medicare Evidence Development & Coverage Advisory Federal Advisory Committee (MEDCAC) provides supplemental expertise to CMS by conducting an unbiased and current review of the latest technology and scientific evidence in order to make a recommendation to CMS. CMS has asked MEDCAC to convene on Wednesday, July 25, 2018 to provide recommendations regarding the state of evidence for procedural volume requirements for hospitals to begin and maintain TAVR programs, especially pertaining to surgical aortic valve replacements (SAVRs), transcatheter aortic valve replacements (TAVRs), and percutaneous coronary interventions (PCIs). Although the MEDCAC was announced prior to the reopening of the TAVR NCD, it is now part of the NCD formal reconsideration process. The MEDCAC recommendation will be used to inform CMS on the issues raised in the letter requesting the TAVR NCD reconsideration.

What evidence does MEDCAC consider?

MEDCAC evidence includes evaluation of medical literature, technology assessment, clinical trials, and the latest effectiveness data.

Is CMS required to implement the MEDCAC recommendations?

No, CMS is not required to implement the recommendations.

Who participate on the MEDCAC?

A MEDCAC panel typically consists of 15 members including:

- Committee chair
- 1 industry representative (non-voting member)
- 1 patient advocate
- 2 to 3 guest expert panelists (non-voting members)
- The remaining 9 to 10 members are chosen by the CMS from a pool of 100 approved MEDCAC members that have cardiology expertise and/or have expertise in policy or technology review

Can the public participate in the MEDCAC meeting?

Yes. Meetings are open to the public and all materials are posted on the [CMS website](#). The public can also speak at the meeting.

How can I get involved?

Your voice matters! It only takes a few clicks to write to your member of Congress by going through the Heart Valve Voice website, which gives you optional language to use, finds your representatives for you, and sends the message. You can also share your thoughts on social media, contact the media, submit comments to CMS, and more. To learn more visit [Heart Valve Voice US](#).

What is the Heart Valve Disease Policy Task Force?

The Task Force is a coalition of organizations advocating for policy solutions that improve access, research, and awareness on heart valve disease detection and treatment. The members of the Task Force are the [Heart Valve Voice US](#), [Mended Hearts](#), [Association of Black Cardiologists](#), and the [Alliance for Aging Research](#).