



October 15, 2021

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-3372-P2,
P.O. Box 8013,
Baltimore, MD 21244-8013.

Electronic Submission

Dear Administrator Brooks-LaSure:

Heart Valve Voice US is submitting these comments on behalf of the Heart Valve Disease Policy Task Force, which we chair. One in eight people over age 75 suffers from moderate to severe heart valve disease, placing a serious health burden on older Americans. As advocates for these patients, we are dismayed and disappointed in the repeal of Medicare Coverage of Innovative Technology rule.

While there are elements of the MCIT rule we would like to see improved, on balance we believe it would serve the best interests of Medicare beneficiaries in need of innovative treatments for heart valve disease. For many heart valve disease patients, time is of the essence and waiting 9-12 months or more for a new technology to work its way through a current coverage pathway might literally be a matter of life or death.

For many decades, if a heart valve needed to be repaired or replaced, the only option was open heart surgery. This procedure is highly invasive, traumatic on the body, requires multiple days in the hospital, and a six-month recovery period. About 10 years ago, we saw the advent of transcatheter aortic valve replacement procedures, TAVR or TAVI, where the valve is inserted by a catheter through the patient's groin or shoulder. The whole procedure may be completed in 45 minutes and during the Covid-19 pandemic we saw these procedures being done on an outpatient basis. These are truly "breakthrough" technologies and there are many more in the pipeline. There are no drug therapies for heart valve disease. This is why automatic coverage of breakthrough technologies upon approval by the Food and Drug Administration is so important.

We would prefer that CMS implement the MCIT rule as scheduled and propose future modifications to address any deficiencies. This approach, we believe, would be in the best interest of patients while also supporting continued medical innovation. Short of this, we implore CMS to propose a new MCIT rule, or a rule meeting the same objective, as soon as practicable.



We understand that CMS is concerned that the clinical trials conducted under the FDA's Breakthrough designation might not always provide evidence that is relevant to the Medicare population. In the case of heart valve disease, however, clinical trials are very representative of the Medicare population. For example, in the pivotal trial for the first transcatheter aortic valve replacement (TAVR) device, 80 percent of the patients were over 75 years of age. More than half of symptomatic patients with severe aortic stenosis die within two years of diagnosis.

More recently, in the pivotal trial for the MitraClip™ mitral valve repair device, the average age of clinical trial participants was 72. Mitral valve disease affects nearly 10 percent of people over age 75.

As such, we believe there would have been sufficient data to support a coverage decision in an MCIT scenario for these two technologies, and they are representative of additional technologies in the approval pipeline. Clinical trials for other serious medical conditions may not have a similar age profile but perhaps CMS should consider the specific evidence used to gain a Breakthrough approval rather than presuming the evidence to be inadequate. Where a breakthrough technology demonstrates clear evidence of benefit to a Medicare population, CMS should act to provide immediate coverage upon FDA approval.

CMS requests comment on whether existing pathways could accommodate MCIT-like objectives of automatic coverage upon FDA approval. We encourage CMS to work with the FDA to evaluate pathways to enable CMS' Coverage and Access Group to begin assessing interventions that have a high probability of receiving FDA approval, before an approval is formally given. Coverage delays of one to two years after CMS approval have real impacts on the health of beneficiaries. Enabling and providing staff capacity to support Parallel Review processes would better serve the objective of CMS, FDA, Medicare beneficiaries, and industry.

One of the shortcomings of the MCIT rule is a lack of any mandatory evidence gathering. Through better coordination, CMS and FDA could work with manufacturers to establish ongoing evidence collection programs to meet the dual objectives of post-market studies and evidence development supporting coverage. This would require early and frequent engagement among CMS, FDA and manufacturers to align on required evidence for approval and coverage. Under this scenario, compliance would likely increase as well. We believe that the MCIT proposal combined with some of the elements of the Parallel Review program would allow for greater access without compromising the mandatory data collection required under existing approval programs.

As patient advocates, we absolutely support ongoing data gathering to ensure technologies are safe, effective, and serve the best interests of Medicare beneficiaries. This mandatory data collection should be of real-world evidence through a new or existing data registry, such as the STS/ACC Transcatheter Valve Therapy (TVT) Registry (in the case of heart valve technologies),



electronic health records, patient-reported outcomes, or other similar mechanisms. This reconsideration of MCIT also provides an opportune time for CMS to weigh the incorporation of patient preference studies into coverage decisions as supplemental evidence while real-world evidence is gathered.

Likewise, we support CMS' ability to have discretion over removing coverage of a device should it not meet the needs of Medicare beneficiaries.

Regarding the "Reasonable & Necessary" provisions of the rule, we recommend CMS consider this issue separately. When the issue is reconsidered, we feel strongly that any codified definition of "reasonable and necessary" include consideration of patient preferences. We are in an era of patient-focused medical product development and patient-centered research and care. The patient perspective must be incorporated into the coverage paradigm, as well. This would entail CMS establishing criteria for the consideration of patient perspectives and incorporation into coverage determinations.

While we disagree with the decision to repeal the MCIT rule, we appreciate your thoughtful consideration of these issues and your focus on advancing policies that are in the best interest of Medicare beneficiaries. Certainty of coverage of innovative technologies is of utmost importance to the patients we represent, most of whom are of Medicare age. If you would have any questions, please do not hesitate to contact John Lewis at john@heartvalvevoice-us.org or 202-285-5726. Thank you for your consideration.

Respectfully Submitted,

Alliance for Aging Research
Association of Black Cardiologists
HealthyWomen
Heart Valve Voice US
Mended Hearts