



Heart Valve
Voice US

July 31, 2024

Dr. Shantanu Agrawal
Chief Health Officer
Elevance Health

RE: Support for Coverage of Valve-In-Valve Transcatheter Mitral Valve Replacement (TM-ViV) Procedures

Dear Dr. Agrawal,

On behalf of Heart Valve Voice US (HVV-US), we are writing to request that Anthem updates its coverage policy to include valve-in-valve transcatheter mitral valve replacement (TM-ViV), to ensure patients receive timely access to individually tailored treatments in accordance with current scientific standards around less-invasive interventional valvular replacement.

HVV-US is a national non-profit patient advocacy organization dedicated to enhancing the lives of individuals affected by heart valve disease. We aim to help advance public policies and practices that promote access to care so that all patients can receive quality and timely access to treatment.

Earlier this year, a patient from our community in California was identified as meeting the criteria for a TM-ViV procedure, and their multidisciplinary heart team determined it to be an appropriate treatment option. Consequently, the patient was scheduled for the procedure. However, Anthem denied the claim, leading to the patient's removal from the schedule. This denial prompted numerous phone conversations among the patient, the hospital, the physician, and Anthem, causing a delay in care as well as unnecessary burdens on the patient and care team.

Despite the significant time, effort, and resources invested in advocating for the patient, the procedure, which is FDA-approved, was not fully recognized in Anthem's policy. After extensive efforts from both the patient and hospital, Anthem eventually approved the procedure. While this instance is specific to one patient, it reflects a broader issue experienced by many, where prolonged delays and bureaucratic obstacles cause unnecessary consequences and hinder timely access to necessary care.

Current Anthem coverage defines TM-ViV treatment as “investigational” and not medically necessary, despite scientific evidence that it is a safe, effective, and less invasive treatment for high surgical risk patients in need of valve replacement. Indeed, there is an established [clinical precedent](#) for the use of TM-ViV in patients as a first treatment approach.

In recent years, TM-ViV has emerged as a less invasive, alternative treatment for high surgical risk patients. While it is the case that open-heart surgery has been consistently proven as a general standard of care, it would be a disservice to patients to limit alternative care that is better tailored to their specific needs by not providing coverage for [TM-ViV](#).

Recent studies illustrate a high technical success rate for TM-ViV treatment and support its use for high surgical risk patients. [In one sample](#) of 1529 patients who underwent treatment between 2015 and 2019, the procedural success rate was 96.8% with a 16.7% mortality rate 1 year after surgery. Another smaller TM-ViV study yielded a 1-year mortality rate of only [13.7%](#). These studies and many others like them indicate that there have already been a significant number of TM-ViV treatments administered and that they have proven to be an effective alternative to open heart surgery for at-risk patient groups. Providing coverage for this less invasive treatment for high surgical risk patients would be consistent with recent surgical practice and the position of prevailing medical literature.

Additionally, limiting access to less-invasive heart surgery alternatives can place an undue burden on minority patients. Observations from a [2021](#) study indicate that traditional open-heart surgery is less accessible to underserved patients due in part to inadequate health insurance coverage and a lack of access to services. By promoting access to less invasive treatments like TM-ViV, marginalized groups would have greater potential to receive access to treatments

On behalf of California heart valve disease patients, we ask that you modify the SURG.00121 coverage policy to establish better access to heart valve treatment alternatives and provide patients with the operation that will serve them best.

If you have questions or would like to discuss this further, please contact Berkeley Barnett, Director, Policy & Advocacy, Heart Valve Voice US at BBarnett@WoodberryAssociates.com.

Sincerely,

A handwritten signature in cursive script that reads "Berkeley Barnett".

Berkeley Barnett
Director, Policy & Advocacy
Heart Valve Voice US

cc: Ricardo Lara, Health Insurance Commissioner, California Department of Insurance