



Transcatheter Aortic Valve Replacement (TAVR)

Origination: 10/25/12	Revised:	Annual Review: 10/11/18
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Purpose:

The Medical Technology Assessment Committee will review published scientific literature and information from appropriate government regulatory bodies (when available) related to *Transcatheter Aortic Valve Replacement (TAVR)* in order to determine inclusion in the benefit plan.

Compliance Status:

- Food and Drug Administration (*FDA*)
- Centers for Medicare & Medicaid Services (*CMS*)

Recommendation:

A recommendation was made by the MTAC following discussion by committee members based on current literature:

- *Transcatheter Aortic Valve Replacement (TAVR)* is approved as a covered benefit but restricted to Members that meet CMS guidelines (refer to *CMS Decision Memo for TAVR CAG-00430N* for complete details); limit to procedures performed at tertiary care centers. CMS guidelines includes:
 - FDA approved aortic valve and implantation system;
 - Two cardiac surgeons independently examine the patient face-to-face and evaluate the patient's suitability for open aortic valve replacement surgery; and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team;
 - 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;
 - TAVR must be furnished in a hospital with the appropriate infrastructure (refer to *CMS Decision Memo*);
 - The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR;
 - The heart team and hospital are participating in a prospective, national, audited registry;
 - TAVR is covered for uses that are not expressly listed as an FDA approved indication when performed within a clinical study that fulfills specific guidelines (refer to *CMS Decision Memo*)
 - TAVR is not covered for patients in whom existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis.



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Disclaimer Information:

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed to determine coverage for AvMed's benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed makes coverage decisions using these guidelines, along with the Member's benefit document. The use of this guideline is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.

Coverage Issues Guidelines and Medical Technology Assessment Recommendations are developed for selected therapeutic or diagnostic services found to be safe, but proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the AvMed Health Plans service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations.

Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change.