CMS NATIONAL COVERAGE DETERMINATION (NCD) 20.32

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

UPDATED PER JUNE 21, 2019 FINAL DECISION MEMO OF FIRST RECONSIDERATION (CAG-00430R)

EFFECTIVE DATE	June 21, 2019
COVERED INDICATIONS	Symptomatic aortic valve stenosis (AS) when furnished according to a Food and Drug Administration (FDA)-approved indication
PATIENT EVALUATION	Cardiac Surgeon and an Interventional Cardiologist experienced in the care of treatment of aortic stenosis who have: i. Independently examined the patient face-to-face, evaluated the patient's suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy; ii. Documented and made available to the other heart team members the rationale for their clinical judgment
JOINT OPERATORS	The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR
HOSPITAL INFRASTRUCTURE REQUIREMENTS TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:	TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to: a. On-site heart valve surgery and interventional cardiology programs b. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures c. Appropriate volume requirements per the applicable qualifications below
NEW TAVR PROGRAMS	
HOSPITAL REQUIREMENTS The hospital program must have the following:	a. ≥ 50 open heart surgeries in the previous year prior to TAVR program initiation, and; b. ≥ 20 aortic valve related procedures in the 2 years prior to TAVR program initiation, and; c. ≥ 2 physicians with cardiac surgery privileges, and; d. ≥ 1 physician with interventional cardiology privileges, and; e. ≥ 300 percutaneous coronary interventions (PCIs) per year
HEART TEAM REQUIREMENTS The heart team must include:	a. Cardiovascular surgeon with: i. ≥ 100 career open heart surgeries of which ≥ 25 are aortic valve related; and, b. Interventional cardiologist with: i. Professional experience of ≥ 100 career structural heart disease procedures; or, ≥ 30 left-sided structural procedures per year; and, ii. Device-specific training as required by the manufacturer.
EXISTING TAVR PROGRAMS	
HOSPITAL REQUIREMENTS The hospital program must maintain the following:	a. ≥ 50 AVRs (TAVR or SAVR) per year including ≥ 20 TAVR procedures in the prior year ; or, b. ≥ 100 AVRs (TAVR or SAVR) every 2 years, including ≥ 40 TAVR procedures in the prior 2 years; and, c. ≥ 2 physicians with cardiac surgery privileges; and, d. ≥ 1 physician with interventional cardiology privileges, and e. ≥300 percutaneous coronary interventions (PCIs) per year; and

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COVERAGE WITH EVIDENCE DEVELOPMENT (CED)	
CED STATUS	The Centers for Medicare & Medicaid Services (CMS) covers transcatheter aortic valve replacement (TAVR) under Coverage with Evidence Development (CED)
REGISTRY REQUIREMENT	The heart team and hospital are participating in a prospective, national, audited registry that: 1. Consecutively enrolls TAVR 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 CFR Part 46 and 21 CFR Parts 50 & 56.
COVERAGE WITH EVIDENCE DEVELOPMENT (CED) RESEARCH QUESTIONS	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) Specifically for the CED question iv, this must be addressed through a composite metric. For the below CED questions (i-iv), the results must be reported publicly. i. When performed outside a controlled clinical study, 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 morbidity and procedure-related factors contribute to TAVR patients' outcomes?

Reference:

Centers for Medicare and Medicaid Services. National Coverage Determination for Transcatheter Aortic Valve Replacement (TAVR) - 20.32
https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355&ncdver=1&DocID=20.32&bc=gAAAABAAAAAA&

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