Transcatheter Aortic Valve Replacement (TAVR)

Medicare Evidence Development & Coverage Advisory Committee (MEDCAC)

July 25, 2018

Center for Clinical Standards and Quality
Coverage and Analysis Group

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Meeting Purpose

Obtain MEDCAC panel recommendations regarding the appraisal of the state of evidence for surgical aortic valve replacement (SAVR), TAVR, percutaneous coronary intervention (PCI) and other relevant structural heart disease procedural volume requirements:

- For hospitals and heart teams to begin TAVR programs
- For hospitals and heart teams to maintain TAVR programs

Recommendations will be based on scientific evidence assessing procedural volume requirements for hospitals and heart team members with both new and continuing TAVR programs that treat Medicare beneficiaries.

TAVR Background

TAVR is used in treating aortic stenosis. A bioprosthetic valve is inserted via transfemoral, transapical or transaortic approaches using a catheter and implanted in the orifice of the native aortic valve or a failed surgical bioprosthetic aortic valve.

CMS established coverage for TAVR within six months of FDA approval

CMS has approved 24 clinical trials covering TAVR in investigational studies leading to FDA approval of expanded indications

NCD provides for concurrent Medicare coverage of expanded indications

Clinical trials CMS covers continue to explore these and other uses for TAVR

- For use in patients at low risk for SAVR
- In asymptomatic patients
- For severe aortic regurgitation

FDA Approval Timeline

Approval Date	Device	Indication	
		Implant Site	Risk Stratum
11/02/2011	Edwards SAPIEN	Native	Inoperable (transfemoral access only)
10/19/2012	Edwards SAPIEN	Native	High risk (transfemoral access only)
09/23/2013	Edwards SAPIEN	Native	Alternate access labeling expansion
01/17/2014	Medtronic CoreValve	Native	Extreme risk
06/12/2014	Medtronic CoreValve	Native	High risk
06/16/2014	Edwards SAPIEN XT	Native	High risk and above
03/30/2015	Medtronic CoreValve	Valve-in-valve	High risk and above
06/17/2015	Edwards SAPIEN 3	Native	High risk and above
06/22/2015	Medtronic CoreValve Evolut R	Native and valve-in-valve	High risk and above
10/09/2015	Edwards SAPIEN XT	Valve-in-valve	High risk and above
08/18/2016	Edwards SAPIEN XT	Native	Intermediate risk
08/18/2016	Edwards SAPIEN 3	Native	Intermediate risk
03/20/2017	Medtronic CoreValve Evolut PRO	Native and valve-in-valve	High risk and above
06/05/2017	Edwards SAPIEN 3	Valve-in-valve	High risk and above
07/10/2017	Medtronic CoreValve, CoreValve Evolut R, and CoreValve PRO	Native	Intermediate risk

Current Medicare Coverage

National Coverage Determination 20.32: *Transcatheter Aortic Valve Replacement (TAVR)*

- TAVR procedures are covered under Coverage with Evidence Development (CED)
- Section A addresses coverage for the treatment of symptomatic aortic valve stenosis when furnished according to a Food and Drug Administration (FDA)-approved indication.
  - Includes numerous requirements for heart teams and hospitals pertaining to both infrastructure and procedure volume requirements
  - Requires heart teams and hospitals to participate in a prospective, national, audited registry (CMS has approved one registry that meets the NCD requirements, the Society of Thoracic Surgeons (STS)/American College of Cardiology (ACC) Transcatheter Valve Therapy (TVT) Registry)
- Section B addresses coverage for uses that are not expressly listed as an FDA-approved indication
  - Procedures must be performed in clinical studies that meet requirements set forth in the NCD and are approved by CMS.
- Both the STS/ACC TVT Registry and all CMS approved TAVR clinical studies under this NCD are listed on the CMS website at https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR.html.
- TAVR is not covered for patients in whom existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis.

NCD Reconsideration

- Reconsideration of the Current TAVR NCD opened on June 27, 2018
- Resulting from a complete formal request to reconsider the NCD
  - Challenges the inclusion of procedural volume requirements
  - Base coverage on quality outcomes instead of non-TAVR procedural volumes
  - Base program qualification on physician operator education, training and skill
- Timeline
  - Initial 30-day public comment period ends July 27, 2018
  - Proposed decision memorandum due March 27, 2019
  - Second 30-day public comment period begins when proposed decision posted
  - Final decision memorandum due 90 days after proposed decision posted
- More information
  - Tracking sheet: https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=293