CMS.gov

Transcatheter Aortic Valve Replacement

Transcatheter aortic valve replacement (TAVR - also known as TAVI or transcatheter aortic valve implantation) is a new technology for use in treating aortic stenosis. A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the native aortic valve.

CMS issued a Medicare National Coverage Determination on May 1, 2012 which allows coverage of TAVR under Coverage with Evidence Development (CED) with certain conditions. The complete determination is available on our website. As part of CED, we are identifying below the Medicare approved registry and Medicare approved clinical trials which have been reviewed and determined to meet the requirements of coverage.

Decision Memos

Transcatheter Aortic Valve Replacement (05/01/2012 NCD)
Transcatheter Aortic Valve Replacement (06/21/2019 NCD)

Registry Approvals

STS/ACC Transcatheter Valve Therapy (TVT) Registry
ClinicalTrials.gov number: NCT01737528
https://www.ncdr.com/TVT/Home/Default.aspx

Clinical Study Approvals

Study Title: A Prospective rAndomized tRial Assessing the safety and effectiveness of the DurAVR® bIomimetic valve designed for physioloGic flow compared to coMmercial TAVR devices (PARADIGM Trial)
Sponsor: Anteris Technologies Ltd.
Clinicaltrials.gov number: NCT07194265
Investigational Device Exemption (IDE) Number: G220275
CMS Approval Date: 04/27/2026

Study Title: STAR Trial (Siegel Transcatheter Aortic Valve Replacement in Patients With Symptomatic Severe Aortic Stenosis)
Sponsor: MiRus, LLC
Clinicaltrials.gov number: NCT07278310
Investigational Device Exemption (IDE) Number: G240242
CMS Approval Date: 03/27/2026

Study Title: Transcatheter Aortic Valve Replacement using the JenaValve Trilogy™ Heart Valve System for Clinically Significant Aortic Regurgitation in Patients with Left Ventricular Assist Devices (LVAD)
Sponsor: JenaValve Technology, Inc.
Clinicaltrials.gov number: NCT06594705
IDE#: G150035
CMS Approval Date: 09/08/2025

Study Title: Siegel™ Transcatheter Aortic Valve Replacement System (TAVR) Early Feasibility Study
Sponsor: MiRus LLC
Clinicaltrials.gov number: NCT06680427
IDE#: G240242
CMS Approval Date: 03/28/2025

Study Title: Randomized Evaluation of Valve-In-Valve versus Explantation for failed TAVR (REVIVE-TAVR)
Sponsor: Medstar Health Research Institute
Clinicaltrials.gov number: NCT06400342
IDE#: G240164
CMS Approval Date: 02/07/2025

Study Title: A Study to Assess Safety and Effectiveness of the JenaValve Trilogy™ Transcatheter Heart Valve System Versus Surgical Valve Replacement in Patients with Aortic Regurgitation
Sponsor: JenaValve Technology, Inc.
ClinicalTrials.gov number: NCT06608823
IDE #: G240185
CMS Approval Date: 01/08/2025

Study Title: JOURNEY: J-Valve to Treat Aortic Regurgitation via Transcatheter Therapy
Sponsor: JC Medical, Inc.
Clinicaltrials.gov number: NCT06455787
IDE#: G190117
CMS Approval Date: 10/03/2024

Study Title: Evaluation of the Navitor Transcatheter Heart Valve in Low and Intermediate Risk Patients who have Severe, Symptomatic, Aortic Stenosis Requiring Aortic Valve Replacement (ENVISION Clinical Trial)
Sponsor: Abbott
Clinicaltrials.gov number: NCT05932615
Investigational Device Exemption (IDE) Number: G230146
CMS Approval Date: 03/14/2024

Study Title: J-Valve TF Early Feasibility Study
Sponsor: JC Medical, Inc.
Clinicaltrials.gov number: NCT06034028
Investigational Device Exemption (IDE) Number: G190117
CMS Approval Date: 12/21/2023

Study Title: Use of DurAVR™ THV System in Subjects with Severe Aortic Stenosis: Early Feasibility Study
Sponsor: Anteris Technologies Ltd.
Clinicaltrials.gov number: NCT05712161
IDE#: G220275
CMS Approval Date: 07/20/2023

Study Title: Evolut™ EXPAND TAVR II Pivotal Trial
Sponsor: Medtronic

Clinicaltrials.gov number: NCT05149755
Investigational Device Exemption (IDE) Number: G210285
CMS Approval Date: 10/19/2022

Study Title: Safety and Effectiveness of Balloon-Expandable Bioprosthetic SAPIEN X4 Transcatheter Heart Valve
Sponsor: Edwards Lifesciences
Clinicaltrials.gov number: NCT05172960
Investigational Device Exemption (IDE) Number: G210327
CMS Approval Date: 05/31/2022

Study Title: Safety and Effectiveness of Balloon-Expandable Bioprosthetic SAPIEN X4 Transcatheter Heart Valve in Failing Aortic Surgical Bioprosthetic Valves
Sponsor: Edwards Lifesciences
Clinicaltrials.gov number: NCT05172973
Investigational Device Exemption (IDE) Number: G210327
CMS Approval Date: 05/31/2022

Study Title: The PROGRESS Trial: A Prospective, Randomized, Controlled Trial to Assess the Management of Moderate Aortic Stenosis by Clinical Surveillance or Transcatheter Aortic Valve Replacement
Sponsor: Edwards Lifesciences
Clinicaltrials.gov number: NCT04889872
Investigational Device Exemption (IDE) Number: G210075
CMS Approval Date: 09/08/2021

Study Title: Evolut™ EXPAND TAVR I Feasibility Study
Sponsor: Medtronic
Clinicaltrials.gov number: NCT04639258
Investigational Device Exemption (IDE) Number: G200275
CMS Approval Date: 06/03/2021

Study Title: A Study to Assess Safety and Probable Benefit of the Transfemoral JenaValve Pericardial TAVR System in the Treatment of High Surgical Risk Patients with Symptomatic, Severe Aortic Regurgitation (AR)
Sponsor: JenaValve Technology, Inc.
Clinicaltrials.gov number: NCT04415047

Investigational Device Exemption (IDE) Number: G150035
CMS Approval Date: 02/16/2021

Study Title: Evaluation of the Portico NG Transcatheter Aortic Valve in High and Extreme Risk Patients with Symptomatic Severe Aortic Stenosis (Portico NG Approval Study)
Sponsor: Abbott
Clinicaltrials.gov number: NCT04011722
Investigational Device Exemption (IDE) Number: G120263
CMS Approval Date: 03/05/2020

Study Title: Transcatheter Replacement of Stenotic Aortic Valve through Implantation of ACURATE in Subjects InDicatEd for TAVR
Sponsor: Boston Scientific Corporation
Clinicaltrials.gov number: NCT03735667
Investigational Device Exemption (IDE) Number: G190051
CMS Approval Date: 07/03/2019

Study Title: REPRISE IV: Repositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantation of LOTUS Edge Valve System in IntermediatE Surgical Risk Subjects
Sponsor: Boston Scientific
Clinicaltrials.gov number: NCT03618095
Investigational Device Exemption (IDE) Number: G160209
CMS Approval Date: 10/16/2018

Study Title: Transcatheter Aortic Valve Replacement (TAVR) With Medtronic TAVR System in Patients With Severe Bicuspid Aortic Valve Stenosis and at Low Predicted Risk of Mortality With Surgical Aortic Valve Replacement (SAVR)
Sponsor: Medtronic Cardiovascular
Clinicaltrials.gov number: NCT03635424
Investigational Device Exemption (IDE) Number: G160022
CMS Approval Date: 10/10/2018

Study Title: A Prospective, Single-arm, Controlled, Multicenter Study to Establish the Safety and Effectiveness of the CENTERA THV System in Intermediate Risk Patients Who Have Symptomatic, Severe, Calcific, Aortic Stenosis Requiring Aortic Valve Replacement

Sponsor: Edwards Lifesciences
Clinicaltrials.gov number: NCT03517436
Investigational Device Exemption (IDE) Number: G180045
CMS Approval Date: 07/05/2018

Study Title: Strategies to Prevent Transcatheter Heart Valve Dysfunction in Low Risk Transcatheter Aortic Valve Replacement
Sponsor: Medstar Health Research Institute
Clinicaltrials.gov number: NCT03557242
Investigational Device Exemption (IDE) Number: G150207
CMS Approval Date: 06/28/2018

Study Title: Transfemoral Replacement of Aortic Valve with HLT MeriDIAN Valve Early Feasibility Trial (RADIANT)
Sponsor: HLT Inc.
Clinicaltrials.gov number: NCT02799823
Investigational Device Exemption (IDE) Number: G160091
CMS Approval Date: 06/29/2017

Study Title: Evaluation of Transcatheter Aortic Valve Replacement Compared to SurveilLance for Patients With AsYmptomatic Severe Aortic Stenosis
Sponsor: Edwards Lifesciences
Clinicaltrials.gov number: NCT03042104
Investigational Device Exemption (IDE) Number: G160259
CMS Approval Date: 06/05/2017

Study Title: Edwards SAPIEN 3 TVH PARTNER 3 Aortic Valve-in-Valve Trial
Sponsor: Edwards Lifesciences
Clinicaltrials.gov number: NCT03003299
Investigational Device Exemption (IDE) Number: G150278
CMS Approval Date: 01/17/2017

Study Title: Transcatheter Aortic Valve Replacement to UNload the Left ventricle in patients with ADvanced heart failure: a randomized trial (TAVR UNLOAD)
Sponsor: Cardiovascular Research Foundation
ClinicalTrials.gov Number: NCT02661451
Investigational Device Exemption (IDE) Number: G150252
CMS Approval Date: 09/06/2016

Study Title: JenaValve AS EFS study
Sponsor: JenaValve Technology, Inc.
ClinicalTrials.gov Number: NCT02732691
Investigational Device Exemption (IDE) Number: G150035
CMS Approval Date: 07/20/2016

Study Title: JenaValve AR EFS study
Sponsor: JenaValve Technology, Inc.
ClinicalTrials.gov Number: NCT02732704
Investigational Device Exemption (IDE) Number: G150035
CMS Approval Date: 07/12/2016

Study Title: Low Risk TAVR
Sponsor: MedStar Cardiovascular Research Institute
ClinicalTrials.gov Number: NCT02628899
Investigational Device Exemption (IDE) Number: G150207
CMS Approval Date: 07/01/2016

Study Title: Medtronic CoreValve Evolut R US Clinical Study: Evolut 34R Addendum
Sponsor: Medtronic
ClinicalTrials.gov Number: NCT02746809
Investigational Device Exemption (IDE) Number: G140059
CMS Approval Date: 06/06/2016

Study Title: Medtronic Transcatheter Aortic Valve Replacement (TAVR) 2.0 US Clinical Study
Sponsor: Medtronic
ClinicalTrials.gov Number: NCT02738853
Investigational Device Exemption (IDE) Number: G160039
CMS Approval Date: 05/31/2016

Study Title: SAPIEN 3 THV PARTNER 3 Trial
Sponsor: Edwards Lifesciences
ClinicalTrials.gov Number : NCT02675114
Investigational Device Exemption (IDE) Number: G150278
CMS Approval Date: 03/17/2016

Study Title: Medtronic Transcatheter Aortic Valve Replacement (TAVR) with the Medtronic Transcatheter Aortic Valve Replacement System (TAVR) in patients at Low Risk for Surgical Aortic Valve Replacement (SAVR)
Sponsor: Medtronic
ClinicalTrials.gov Number: NCT02701283
Investigational Device Exemption (IDE) Number: G160022
CMS Approval Date: 03/17/2016

Study Title: REPRISE III: REpositionable Percutaneous Replacement of Stenotic Aortic Valve through Implantation of Lotus™ Valve System – Randomized Clinical Evaluation
Sponsor: Boston Scientific Corporation
ClinicalTrials.gov Number : NCT02202434
Investigational Device Exemption (IDE) Number: G140090
CMS Approval Date: 09/13/2014

Study Title: The Medtronic CoreValve™ Evolut R™ Clinical Study
Sponsor: Medtronic
ClinicalTrials.gov Number: NCT02207569
Investigational Device Exemption (IDE) Number: G140059
CMS Approval Date: 07/24/2014

Study Title: TranScatheter Aortic Valve RepLacement System a US Pivotal Trial (SALUS)
Sponsor: Direct Flow Medical, Inc.
ClinicalTrials.gov Number: NCT02163850
Investigational Device Exemption (IDE) Number: G120160
CMS Approval Date: 06/05/2014

Study Title: Portico Re-sheathable Transcatheter Aortic Valve System US IDE Trial (PORTICO) Interventional Trial
Sponsor: St. Jude Medical
ClinicalTrials.gov Number: NCT02000115
Investigational Device Exemption (IDE) Number: G120263
CMS Approval Date: 03/25/2014

Study Title: SALUS Trial: The Direct Flow Medical Transcatherter Aortic Valve Replacement System US Feasibility Trial

Sponsor: Direct Flow Medical
ClinicalTrials.gov Number: NCT01932099
Investigational Device Exemption (IDE) Number: G120160
CMS Approval Date: 09/25/2013

Study Title: Alternative Access Approaches for Transcatheter Aortic Valve Replace (TAVR) in Inoperable Patients with Aortic Stenosis
Sponsor: The Society of Thoracic Surgeons and The American College of Cardiology Foundation
ClinicalTrials.gov Number: NCT01787084
Investigational Device Exemption (IDE) Number: G120291
CMS Approval Date: 02/07/2013

Study Title: Medtronic CoreValve Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI)
Sponsor: Medtronic
ClinicalTrials.gov Number: NCT01586910
Investigational Device Exemption (IDE) Number: G120169
CMS Approval Date: 09/05/2012

Study Title: Medtronic CoreValve Expanded Use Study
Sponsor: Medtronic
ClinicalTrials.gov Number: NCT01675440
Investigational Device Exemption (IDE) Number: G100012
CMS Approval Date: 09/11/2012

Study Title: PARTNER II Trial (Placement of AoRTic TraNscathetER Valves Trial II)
Sponsor: Edwards Lifesciences
ClinicalTrials.gov Number: NCT01314313
Investigational Device Exemption (IDE) Number: G090216
CMS Approval Date: 05/01/2012

Study Title: Medtronic CoreValve U.S. Pivotal Trial
Sponsor: Medtronic
ClinicalTrials.gov Number: NCT01240902
Investigational Device Exemption (IDE) Number: G100012
CMS Approval Date: 05/01/2012

Study Title: Medtronic CoreValve Continued Access Study
Sponsor: Medtronic
ClinicalTrials.gov Number: NCT01531374
Investigational Device Exemption (IDE) Number: G100012
CMS Approval Date: 05/01/2012

Related Links

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