

Transcatheter Aortic Valve Replacement (TAVR) (NCD 20.32)

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[↪ Terms and Conditions](#)

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Related Medicare Advantage Coverage Summaries

- [Experimental Procedures and Items, Investigational Devices and Clinical Trials](#)
- [Transcatheter Heart Valve Procedures](#)

Policy Summary

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Overview

Transcatheter aortic valve replacement (TAVR-also known as TAVI or transcatheter aortic valve implantation) is used in the treatment of aortic stenosis. A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the aortic valve.

Guidelines

Nationally Covered Indications

United Health Care covers transcatheter aortic valve replacement (TAVR) under Coverage with Evidence Development (CED) with the following conditions:

TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to a Food and Drug Administration (FDA)-approved indication and when all of the following conditions are met:

- The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval (PMA) for that system's FDA approved indication.
- The patient (preoperatively and postoperatively) 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. The heart team includes the following:
 - Cardiac surgeon and an interventional cardiologist experienced in the care and treatment of aortic stenosis who have:
 - Independently examined the patient face-to-face, evaluated the patient's suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy;
 - Documented and made available to the other heart team members the rationale for their clinical judgment.
 - Providers from other physician groups as well as advanced patient practitioners, nurses, research personnel and administrators.
- The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:

- On-site heart valve surgery and interventional cardiology programs,

- Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures,
- Appropriate volume requirements per the applicable qualifications below.

There are two sets of qualifications; the first set outlined below is for hospital programs and heart teams without previous TAVR experience and the second set is for those with TAVR experience.

Qualifications to begin a TAVR program for hospitals without TAVR experience:

- The hospital program must have the following:
 - ≥ 50 total open heart surgeries in the previous year prior to TAVR, program initiation, and;
 - ≥ 20 aortic valve related procedures in the 2 years prior to TAVR program initiation, and;
 - ≥ 2 physicians with cardiac surgery privileges, and;
 - ≥ 1 physician with interventional cardiology privileges, and;
 - ≥ 300 percutaneous coronary interventions (PCIs) per year.

Qualifications to begin a TAVR program for heart teams without TAVR experience:

- The heart team must include:
 - Cardiovascular surgeon with:
 - ≥ 100 career open heart surgeries of which ≥ 25 are aortic valve related;
 - Interventional cardiologist with:
 - Professional experience of ≥ 100 career structural heart disease procedures lifetime; or,
 - ≥ 30 left-sided structural procedures per year; and,
 - Device-specific training as required by the manufacturer.

Qualifications for hospital programs with TAVR experience:

- The hospital program must maintain the following:
 - ≥ 50 AVRs (TAVR or SAVR) per year including ≥ 20 TAVR procedures in the prior year ; or,
 - ≥ 100 AVRs (TAVR or SAVR) every 2 years, including ≥ 40 TAVR procedures in the prior 2 years; and,
 - ≥ 2 physicians with cardiac surgery privileges; and,
 - ≥ 1 physician with interventional cardiology privileges, and
 - ≥ 300 percutaneous coronary interventions (PCIs) per year
- 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. The following outcomes must be tracked by the registry; and the registry must be designed to permit identification and analysis of patient, practitioner and facility level variables that predict each of these outcomes:
 - Stroke;
 - All cause mortality;
 - Transient Ischemic Attacks (TIAs);
 - Major vascular events;
 - Acute kidney injury;
 - Repeat aortic valve procedures;
 - New permanent pacemaker implantation;
 - Quality of Life (QoL).

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 as described in research study protocols below

- When performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?
- What is the long term durability of the device?
- What are the long term outcomes and adverse events?
- What morbidity and procedure-related factors contribute to TAVR patients outcomes?

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

TAVR is covered for uses that are not expressly listed as an FDA-approved indication when performed within a clinical study that fulfills all of the following:

- The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.
- As a fully-described, written part of its protocol, the clinical research study must critically evaluate not only each patient's quality of life pre- and post-TAVR (minimum of 1 year), but must also address at least one of the following questions:
 - What is the incidence of stroke?
 - What is the rate of all cause mortality?
 - What is the incidence of new permanent pacemaker implantation?
 - What is the incidence of transient ischemic attacks (TIAs)?
 - What is the incidence of major vascular events?
 - What is the incidence of acute kidney injury?
 - What is the incidence of repeat aortic valve procedures?
- The clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:
 - a. The principal purpose of the study is to test whether a particular item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
 - b. The rationale for the study is well supported by available scientific and medical evidence.
 - c. The study results are not anticipated to unjustifiably duplicate existing knowledge.
 - d. The research study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
 - e. The research study is sponsored by an organization or individual capable of completing it successfully.
 - f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it also must be in compliance with 21 CFR Parts 50 and 56. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and /or services, and the use and eventual disposition of the collected data.
 - g. All aspects of the research study are conducted according to appropriate standards of scientific integrity.
 - h. The research study has a written protocol that clearly demonstrates adherence to the standards listed as Medicare coverage requirements.
 - i. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals.
 - j. The clinical research study is registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR).
 - k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessible manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).
 - l. The study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

- m. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility. Consistent with section 1142 of the Act, AHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that meet the above-listed standards and address the above-listed research questions.

The principal investigator must submit the complete study protocol, identify the relevant CMS research question(s) that will be addressed, and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS Website.

Director, Coverage and Analysis Group

Re: TAVR CED

Centers for Medicare & Medicaid Services (CMS)

7500 Security Blvd., Mail Stop S3-02-01

Baltimore, MD 21244-1850

Email address for protocol submissions: clinicalstudynotification@cms.hhs.gov

Email subject line: "CED [NCD topic (i.e., TAVR)] [name of sponsor/primary investigator]"

Nationally Non-Covered Indications

TAVR is not covered for patients in whom existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| CPT Code | Description |
|----------|--|
| 33361 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach |
| 33362 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach |
| 33363 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach |
| 33364 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach |
| 33365 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy) |
| 33366 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure |
| 33367 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., femoral vessels) (List separately in addition to code for primary procedure) |
| 33368 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with open peripheral arterial and venous cannulation (e.g., femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure) |

| CPT Code | Description |
|----------|---|
| 33369 | Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with central arterial and venous cannulation (e.g., aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure) |

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| Modifier | Description |
|----------|---|
| 62 | Two surgeons |
| Q0 | Investigational clinical service provided in a clinical research study that is in an approved clinical research study |

| Condition Code | Description |
|----------------|---------------------------|
| 30 | Qualifying clinical trial |

| Place of Service Code | Description |
|-----------------------|-------------|
| 21 | Inpatient |

| Diagnosis Code | Description |
|----------------|--|
| Z00.6 | Encounter for examination for normal comparison and control in clinical research program |

| ICD Procedure Code | Description |
|--------------------|--|
| 02RF37H | Replacement of aortic valve with autologous tissue substitute, transapical, percutaneous approach |
| 02RF37Z | Replacement of aortic valve with autologous tissue substitute, percutaneous approach |
| 02RF38H | Replacement of aortic valve with zooplastic tissue, transapical, percutaneous approach |
| 02RF38Z | Replacement of aortic valve with zooplastic tissue, percutaneous approach |
| 02RF3JH | Replacement of aortic valve with synthetic substitute, transapical, percutaneous approach |
| 02RF3JZ | Replacement of aortic valve with synthetic substitute, percutaneous approach |
| 02RF3KH | Replacement of aortic valve with nonautologous tissue substitute, transapical, percutaneous approach |
| 02RF3KZ | Replacement of aortic valve with nonautologous tissue substitute, percutaneous approach |

References

CMS National Coverage Determinations (NCDs)

[NCD 20.32 Transcatheter Aortic Valve Replacement \(TAVR\)](#)

CMS Benefit Policy Manual

[Chapter 14: § 10 Coverage of Medical Devices, § 20 FDA Approval Investigational Device Exemptions \(IDEs\), § 30 Coverage of FDA-Approved IDEs, § 40 Providers Seeking Reimbursement for Investigational Devices, § 50 Coverage Requirements, § 70 Payment for IDE Category B Devices](#)

CMS Claims Processing Manual

[Chapter 32; § 290.1 Coding Requirements for TAVR Furnished on or after May 1, 2012, § 290.1.1 Coding Requirements for TAVR Services Furnished on or after January 1, 2013, § 290.2 Claims Processing Requirements for TAVR Services on Professional Claims, § 290.3 Claims Processing Requirements for TAVR Services on Inpatient Hospital Claims, § 290.4 Claims Processing Requirements for TAVR Services for Medicare Advantage \(MA\) Plan Participants](#)

CMS Transmittal(s)

[Transmittal 147, Change Request 7997, Dated 09/24/2012, \(National Coverage Determination \(NCD\) for Transcatheter Aortic Valve Replacement \(TAVR\); related to TAVR Medicare Approved Facilities](#)
[Transmittal 2512, Change Request 7897, Dated 08/03/2012 \(National Coverage Determination \(NCD\) for Transcatheter Aortic Valve Replacement \(TAVR\)](#)
[Transmittal 2552, Change Request 7897, Dated 09/24/2012 \(National Coverage Determination \(NCD\) for Transcatheter Aortic Valve Replacement \(TAVR\)](#)
[Transmittal 2628, Change Request 8168, Dated 01/07/2013 \(Transcatheter Aortic Valve Replacement \(TAVR\) Coding Update/Policy Clarification\)](#)
[Transmittal 2737, Change Request 8255, Dated 07/11/2013 \(National Coverage Determination \(NCD\) for Transcatheter Aortic Valve Replacement \(TAVR\) – Implementation of Mandatory Reporting of Clinical Trial Number\)](#)
[Transmittal 2827, Change Request 8537, Dated 11/29/2013 \(Transcatheter aortic valve replacement \(TAVR\)-Implementation of Permanent CPT Code\)](#)

MLN Matters

[Article MM7897, National Coverage Determination \(NCD\) for Transcatheter Aortic Valve Replacement \(TAVR\)](#)
[Article MM8168, National Coverage Determination \(NCD\): Transcatheter Aortic Valve Replacement \(TAVR\) Coding Update/Policy Clarification](#)
[Article MM8255, National Coverage Determination \(NCD\) for Transcatheter Aortic Valve Replacement \(TAVR\)-Implementation of Mandatory Reporting of Clinical Trial Number](#)
[Article MM8537, Transcatheter Aortic Valve Replacement \(TAVR\)-Implementation of Permanent CPT Code](#)

UnitedHealthcare Commercial Policy

[Transcatheter Heart Valve Procedures](#)

Other(s)

[Medicare Approved Facilities/Trials/Registries \(TAVR Medicare Approved Facilities\), CMS Website](#)
[Participant Directory \(TAVR Medicare Approved Facilities\), NCDR Website](#)
[Transcatheter Aortic Valve Replacement \(TAVR\) Posted final decision memo](#)

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

| Date | Summary of Changes |
|------------|---|
| 04/01/2021 | Template Update <ul style="list-style-type: none">Reformatted policy; transferred content to new template |
| 03/10/2021 | Policy Summary <i>Nationally Covered Indications</i> <ul style="list-style-type: none">Revised list of qualifications to begin a TAVR heart program for heart teams without TAVR experience: replaced “interventional cardiologist with professional experience of 100 career structural heart disease procedures [in a] lifetime” with “interventional cardiologist with professional experience of \geq [<i>greater than or equal to</i>] 100 career structural heart disease procedures [in a] lifetime”Added language to indicate, consistent with <i>Section §1142 of the Social Security Act</i>, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that meet the standards and address the research questions [listed in the policy] Supporting Information <ul style="list-style-type: none">Archived previous policy version MPG310.06 |

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).