INSTRUCTIONS FOR USE

This Policy Guideline is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates for health care services submitted on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450), or their electronic comparative. The information presented in this Policy Guideline is believed to be accurate and current as of the date of publication.

This Policy Guideline provides assistance in administering health benefits. All reviewers must first identify member eligibility, any federal or state regulatory requirements, Centers for Medicare and Medicaid Services (CMS) policy, the member specific benefit plan coverage, and individual provider contracts prior to use of this Policy Guideline. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document may differ greatly from the standard benefit plan upon which this Policy Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Policy Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

UnitedHealthcare follows Medicare coverage guidelines and regularly updates its Medicare Advantage Policy Guidelines to comply with changes in CMS policy. UnitedHealthcare encourages physicians and other healthcare professionals to keep current with any CMS policy changes and/or billing requirements by referring to the CMS or your local carrier website regularly. Physicians and other healthcare professionals can sign up for regular distributions for policy or regulatory changes directly from CMS and/or your local carrier.

This Policy Guideline is provided for informational purposes. It does not constitute medical advice.

POLICY SUMMARY

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.
- Two cardiac surgeons have independently examined the patient face-to-face and evaluated the patient's suitability for open aortic valve replacement (AVR) surgery; and both surgeons have documented the rationale for their clinical judgment and the rationale is available to the heart team.
- 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.
TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:
- On-site heart valve surgery program,
- Cardiac catheterization lab or hybrid operating room/catheterization lab equipped with a fixed radiographic imaging system with flat-panel fluoroscopy, offering quality imaging,
- Non-invasive imaging such as echocardiography, vascular ultrasound, computed tomography (CT) and magnetic resonance (MR),
- Sufficient space, in a sterile environment, to accommodate necessary equipment for cases with and without complications,
- 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 AVRs in the previous year prior to TAVR, including 10 high-risk patients, and;
  - ≥ 2 physicians with cardiac surgery privileges, and;
  - ≥ 1000 catheterizations per year, including 400 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 AVRs including 10 high-risk patients; or,
    - ≥ 25 AVRs in one year; or,
    - ≥ 50 AVRs in 2 years; and which include at least 20 AVRs in the last year prior to TAVR initiation; and,
  - Interventional cardiologist with:
    - Professional experience with 100 structural heart disease procedures lifetime; or,
    - 30 left-sided structural procedures per year of which 60% should be balloon aortic valvuloplasty (BAV). Atrial septal defect and patent foramen ovale closure are not considered left-sided procedures; and,
  - Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers; and,
  - Device-specific training as required by the manufacturer.

Qualifications for hospital programs with TAVR experience:
- The hospital program must maintain the following:
  - ≥ 20 AVRs per year or ≥ 40 AVRs every 2 years; and,
  - ≥ 2 physicians with cardiac surgery privileges; and,
  - ≥ 1000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year.

Qualifications for heart teams with TAVR experience:
- The heart team must include:
  - Cardiovascular surgeon and an interventional cardiologist whose combined experience maintains the following:
    - ≥ 20 TAVR procedures in the prior year, or,
    - ≥ 40 TAVR procedures in the prior 2 years; and,
  - Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers.
  - 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 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;
Quality of Life (QoL).

The registry should 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):

- When performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?
- How do outcomes and adverse events in subpopulations compare to patients in the pivotal clinical studies?
- What is the long term (5 year) durability of the device?
- What are the long term (5 year) outcomes and adverse events?
- How do the demographics of registry patients compare to the pivotal studies?

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 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:
  - The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
  - The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
  - The research study does not unjustifiably duplicate existing studies.
  - The research study design is appropriate to answer the research question being asked in the study.
  - The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- 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. In particular, the informed consent includes a straightforward explanation of the reported increased risks of stroke and vascular complications that have been published for TAVR.
- All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).
- The research study has a written protocol that clearly addresses, or incorporates by reference; the standards listed as Medicare coverage requirements.
- The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard 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 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.
- 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 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (http://www.icmje.org). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.
- The research 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.

- The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. 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.

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

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 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.

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<tr>
<th>CPT Code</th>
<th>Description</th>
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<tr>
<td>33361</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach</td>
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<tr>
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<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach</td>
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<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach</td>
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<td>33364</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach</td>
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<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)</td>
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<tr>
<td>33366</td>
<td>Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure</td>
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<tr>
<td>33367</td>
<td>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)</td>
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<tr>
<td>33368</td>
<td>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)</td>
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<tr>
<td>33369</td>
<td>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)</td>
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*CPT® is a registered trademark of the American Medical Association*
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<td>Investigational clinical service provided in a clinical research study that is in an approved clinical research study</td>
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<td>Routine clinical service provided in a clinical research study that is in an approved clinical research study</td>
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<th>ICD-10 Diagnosis Code</th>
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<tr>
<td>Z00.6</td>
<td>Encounter for examination for normal comparison and control in clinical research program</td>
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<td>02RF37H</td>
<td>Replacement of aortic valve with autologous tissue substitute, transapical, percutaneous approach</td>
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<td>02RF37Z</td>
<td>Replacement of aortic valve with autologous tissue substitute, percutaneous approach</td>
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<td>02RF38H</td>
<td>Replacement of aortic valve with zooplastic tissue, transapical, percutaneous approach</td>
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<td>02RF38Z</td>
<td>Replacement of aortic valve with zooplastic tissue, percutaneous approach</td>
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<td>02RF3JH</td>
<td>Replacement of aortic valve with synthetic substitute, transapical, percutaneous approach</td>
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<td>02RF3JZ</td>
<td>Replacement of aortic valve with synthetic substitute, percutaneous approach</td>
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<td>02RF3KH</td>
<td>Replacement of aortic valve with nonautologous tissue substitute, transapical, percutaneous approach</td>
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<tr>
<td>02RF3KZ</td>
<td>Replacement of aortic valve with nonautologous tissue substitute, percutaneous approach</td>
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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 Transmittals
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
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 Policies
Transcatheter Heart Valve Procedures

Others
Medicare Approved Facilities/Trials/Registries (TAVR Medicare Approved Facilities), CMS Website
Participant Directory (TAVR Medicare Approved Facilities), NCDR Website

GUIDELINE HISTORY/REVISION INFORMATION

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<tr>
<th>Date</th>
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