# Coverage Summary

## Transcatheter Heart Valve Procedures

<table>
<thead>
<tr>
<th>Policy Number:</th>
<th>T-007</th>
<th>Products:</th>
<th>UnitedHealthcare Medicare Advantage Plans</th>
<th>Original Approval Date:</th>
<th>06/18/2012</th>
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<tr>
<td>Approved by:</td>
<td>UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date:</td>
<td>06/21/2017</td>
<td></td>
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</tr>
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</table>

Related Medicare Advantage Policy Guidelines:

- Percutaneous Left Atrial Appendage Closure (LAAC) (NCD 20.34)
- Transcatheter Mitral Valve Repair (TMVR) (NCD 20.33)
- Transcatheter Aortic Valve Replacement (TAVR) (NCD 20.32)

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**Coverage Statement:** Transcatheter heart valve replacement may be covered when Medicare coverage criteria are met.

**Guidelines/Notes:**

1. **Transcatheter Aortic Valve Replacement (TAVR)**
   - Medicare covers transcatheter aortic valve replacement (TAVR) under Coverage with Evidence Development (CED) when criteria are met.

   See the National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) (20.32). Local Coverage Determinations (LCDs) do not exist at this time. (Accessed May 23, 2017)

   - CMS considers TAVR as Category B devices and UnitedHealthcare MA plan is responsible...
for coverage of these devices when criteria are met. Refer to the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials for coverage guidelines on Category B devices.

- To view the list of current Transcatheter Valve Therapy (TVT) Registry participants, go to https://www.ncdr.com/TVT/Private/Resources/ParticipantDirectory.aspx or contact the TVT Registry Service Center at (800) 257-4737. (Accessed May 23, 2017)
- For payment rules for NCDs requiring CED, see the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials.

The following guidelines are based on the Transcatheter Aortic Valve Replacement (TAVR) (20.32). (Accessed May 23, 2017)

a. **TAVR is covered** for the treatment of symptomatic aortic valve stenosis when furnished according to an FDA approved indication and when all of the following conditions are met. (Note: Refer to Section II Definitions for the TAVR device FDA approval information, indications/contraindications for use and other FDA related information.)

1) 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.

2) 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.

3) 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:
  a. $\geq 50$ total AVRs in the previous year prior to TAVR, including $\geq 10$ high-risk patients, and;
  b. $\geq 2$ physicians with cardiac surgery privileges, and;
  c. $\geq 1000$ catheterizations per year, including $\geq 400$ percutaneous coronary interventions (PCIs) per year.

- **Qualifications to begin a TAVR program for heart teams without TAVR experience:** The heart team must include:
  a. Cardiovascular surgeon with:
     i. $\geq 100$ career AVRs including 10 high-risk patients; or
     ii. $\geq 25$ AVRs in one year; or
     iii. $\geq 50$ AVRs in 2 years; and which include at least 20 AVRs in the last year prior to TAVR initiation; and
  b. Interventional cardiologist with:
     i. Professional experience with 100 structural heart disease procedures lifetime; or;
     ii. 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
  c. Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers; and
  d. Device-specific training as required by the manufacturer.

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

- **Qualifications for heart teams with TAVR experience:**
  The heart team must include:
  a. A cardiovascular surgeon and an interventional cardiologist whose combined experience maintains the following:
     i. $\geq 20$ TAVR procedures in the prior year, or;
     ii. $\geq 40$ TAVR procedures in the prior 2 years; and
  b. Additional members of the heart team such as echocardiographers, imaging specialists, heart failure specialists, cardiac anesthesiologists, intensivists, nurses, and social workers.

4. The heart team’s interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

5. 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:

i. Stroke;

ii. All cause mortality;

iii. Transient Ischemic Attacks (TIAs);

iv. Major vascular events;

v. Acute kidney injury;

vi. Repeat aortic valve procedures;

vii. 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.

b. **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:**

*(Note: Refer to Section II (Definitions) for the TAVR device FDA approval information, indications/contraindications for use and other FDA related information.)*

1) The heart team’s interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

2) 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?

3) 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.

   a. 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.
b. The research study does not unjustifiably duplicate existing studies.

c. The research study design is appropriate to answer the research question being asked in the study.

d. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.

e. 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.

f. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).

g. The research study has a written protocol that clearly addresses, or incorporates by reference; the standards listed as Medicare coverage requirements.

h. 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.

i. 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.

j. The research study protocol specifies the method and timing of public release of all prespecified 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 that 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.

k. 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.

l. 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, 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.

4) 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

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

2. **Transcatheter Mitral Valve Repair (e.g., MitraClip®)**
   The Centers for Medicare & Medicaid Services (CMS) covers transcatheter mitral valve repair (TMVR) under Coverage with Evidence Development (CED). For coverage requirements and criteria, refer to the *NCD for Transcatheter Mitral Valve Repair (TMVR) (20.33)* (Accessed May 23, 2017)

   The list of Medicare approved clinical trials is available at  
   (Accessed May 23, 2017)

   For payment rules for NCDs requiring CED, see the [Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials](#).

3. **Transcatheter Pulmonary Valve Replacement (e.g., Melody®) (CPT Code 33477)**
   - Medicare does not have an NCD for transcatheter pulmonary heart valve replacement.
   - Local Coverage Determinations (LCDs) and Local Articles exist and compliance with these LCDs is required where applicable. For state-specific LCDs, see the [LCD Availability Grid (Attachment A)](#).
   - **For states with no LCDs**, refer to the *UnitedHealthcare Medical Policy for Transcatheter Heart Valve Procedures* for coverage guidelines. *(IMPORTANT NOTE: After searching the Medicare Coverage Database, if no state LCD or Local Article is found, then use the above referenced policy.)*
   - **Committee approval date:** June 20, 2017
   - Accessed May 24, 2017

4. **Percutaneous Left Atrial Appendage (LAA) Closure Therapy** (CPT code 33340)
   The Centers for Medicare & Medicaid Services (CMS) covers percutaneous left atrial appendage closure (LAAC) for non-valvular atrial fibrillation (NVAF) through Coverage with Evidence Development (CED) under 1862(a)(1)(E) of the Social Security Act.

   See the *NCD for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34)*. *(Accessed May 23, 2017)*
II. DEFINITIONS

TAVR Device FDA Approval Information: On November 2, 2011 the Food and Drug Administration (FDA) approved the first TAVR device for marketing in the United States. The Edwards’ Sapien Transcatheter Heart Valve (THV) was approved “for transfemoral delivery in patients with severe symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis”

Indications for Use: The Edwards SAPIEN Transcatheter Heart Valve (THV), model 9000TFX, sizes 23mm and 26mm, is indicated for transfemoral delivery in patients with severe symptomatic native aortic valve stenosis who have been determined by a cardiac surgeon to be inoperable for open aortic valve replacement and in whom existing co-morbidities would not preclude the expected benefit from correction of the aortic stenosis.

Contraindications: The bioprosthesis and delivery system are contraindicated in patients who cannot tolerate an anticoagulation/antiplatelet regimen or who have active bacterial endocarditis or other active infections.


III. REFERENCES

See above

IV. REVISION HISTORY

06/21/2017 Annual review; no updates.

01/17/2017 Re-review with the following recommended update:
Guideline 4 [Percutaneous Left Atrial Appendage (LAA) Closure Therapy] – deleted CPT code 0281T and added new replacement CPT code 33340 (effective 1/1/2017)

06/21/2016 Annual-review with following update:
Guideline 4 (Percutaneous Left Atrial Appendage (LAA) Closure Therapy) – Removed reference to the “CMS Decision Memo for Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CAG-00445N)” and in its place added reference to the “NCD for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34).”

02/16/2016 Re-review with following updates:
• Guideline 2 (Transcatheter Pulmonary Valve Replacement)
  o Replaced CPT code 0262T with CPT code 33477
  o Added the following language: “and compliance with these LCDs is required where applicable. For state-specific LCDs”
• Guideline 4 (Percutaneous Left Atrial Appendage (LAA) Closure Therapy) –
Added the following guideline (new to the policy):

“On February 8, 2016, the Centers for Medicare & Medicaid Services (CMS) issue a final decision memo pertaining to the coverage of percutaneous left atrial appendage closure (LAAC) for non-valvular atrial fibrillation (NVAF) through Coverage with Evidence Development (CED) under 1862(a)(1)(E) of the Social Security Act.


All Medicare approved registries will be listed on the CED website located at https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html. (Accessed June 3, 2016)

For payment rules for NCDs requiring CED, see the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials.

- Updated reference link(s) of the applicable LCDs to reflect the condensed link.

06/16/2015 Annual review with the following updates:
- Guideline #2 (Transcatheter Mitral Valve Repair (e.g., MitraClip®)- Deleted reference to LCDs/Local Articles for MitraClip® Percutaneous Mitral Valve Repair System and MitraClip Investigational Device Exemptions (IDEs) Billing and Coding Guidelines, as they are no longer available.
- Guideline #3 [Transcatheter Pulmonary Valve Replacement (e.g., Melody®) (CPT Code 0262T)] - Added following language “(IMPORTANT NOTE: After searching the Medicare Coverage Database, if no state LCD or Local Article is found, then use the above referenced policy.)” under section titled “For states with no LCDs”.

04/21/2015 Re- review with following updates:
Guideline #1 (Transcatheter Aortic Valve Replacement)
- Added reference link to the NCD for Transcatheter Mitral Valve Repair (TMVR) (20.33).
- Added reference link to the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials for payment rules for NCDs requiring CED.
Guideline #2 (Transcatheter Mitral Valve Repair)
- Added reference link to the list of Medicare approved clinical trials.
- Added reference link to the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials for payment rules for NCDs requiring CED.

11/18/2014 Guideline 2 (Transcatheter Mitral Valve Repair)
Changed default guideline from the UnitedHealthcare Medical Policy for Transcatheter Heart Valve Procedure to the new CMS NCD for Transcatheter Mitral Valve Repair (TMVR).

05/20/2014 Annual review with the following updates:
- Policy title changed to “Transcatheter Heart Valve Procedures”.
- Guideline #2 (Transcatheter Mitral Valve Repair) - Added applicable coverage
- Guideline #3 (Transcatheter Pulmonary Valve Replacement) - Added applicable coverage guidelines (new to policy).

## V. ATTACHMENT

### Attachment A - LCD Availability Grid

**Transcatheter Pulmonary Valve Replacement**

(CPT code 33477)

CMS website accessed May 24, 2017

**IMPORTANT NOTE:** Use the applicable LCD based on member’s residence/place of service AND type of service.

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<tr>
<th>LCD ID</th>
<th>LCD Title</th>
<th>Contractor Type</th>
<th>Contractor</th>
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</tr>
</thead>
<tbody>
<tr>
<td>L33777</td>
<td>Noncovered Services</td>
<td>A and B MAC</td>
<td>First Coast Service Options, Inc.</td>
<td>FL, PR, VI</td>
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<tr>
<td>L35094</td>
<td>Services That Are Not Reasonable and Necessary</td>
<td>A and B MAC</td>
<td>Novitas Solutions, Inc.</td>
<td>AR, CO, DC, DE, LA, MA, MS, NJ, NM, OK, PA, TX</td>
</tr>
</tbody>
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End of Attachment A