### Coverage Summary

#### Transcatheter Heart Valve Procedures

<table>
<thead>
<tr>
<th>Policy Number: T-007</th>
<th>Products: UnitedHealthcare Medicare Advantage Plans</th>
<th>Original Approval Date: 06/18/2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date: 06/19/2018</td>
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**Related Medicare Advantage Policy Guidelines:**
- Percutaneous Left Atrial Appendage Closure (LAAC) (NCD 20.34)
- Transcatheter Aortic Valve Replacement (TAVR) (NCD 20.32)
- Transcatheter Mitral Valve Repair (TMVR) (NCD 20.33)

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This information is being distributed to you for personal reference. The information belongs to UnitedHealthcare and unauthorized copying, use, and distribution are prohibited. This information is intended to serve only as a general reference resource and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Each benefit plan contains its own specific provisions for coverage, limitations, and exclusions as stated in the Member’s Evidence of Coverage (EOC)/Summary of Benefits (SB). If there is a discrepancy between this policy and the member’s EOC/SB, the member’s EOC/SB provision will govern. The information contained in this document is believed to be current as of the date noted.

The benefit information in this Coverage Summary is based on existing national coverage policy, however Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable.

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**I. COVERAGE**

**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 June 6, 2018)*
• 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 June 6, 2018)

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

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 June 11, 2018)


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

3. Transcatheter Pulmonary Heart Valve Replacement (e.g., Melody®) (CPT Code 33477)
• Medicare does not have an NCD for transcatheter pulmonary heart valve replacement.

• Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For state-specific LCDs/LCAs, see the LCD Availability Grid (Attachment A).

• For states with no LCDs/LCAs, refer to the UnitedHealthcare Medical Policy for Transcatheter Heart Valve Procedures for coverage guidelines. (IMPORTANT NOTE: After reviewing the LCD Availability Grid and searching the Medicare Coverage Database, if no state LCD or LCA is found, then use the above referenced policy.)

• Committee approval date: June 19, 2018

• Accessed June 11, 2018

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 June 11, 2018)

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 11, 2018)

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

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)
  - Replaced CPT code 0262T with CPT code 33477
  - 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) –

06/21/2018 Annual review with the following update:
Guideline 1 [Transcatheter Aortic Valve Replacement (TAVR)] – deleted detailed guidelines as the same exact guidelines are in the reference National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement (TAVR) (20.32).

06/21/2016 Annual review with following updates:
Guideline 2 (Transcatheter Pulmonary Valve Replacement) –
- Replaced CPT code 0262T with CPT code 33477
- Added the following language: “and compliance with these LCDs is required where applicable. For state-specific LCDs”

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)
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
guidelines (new to policy).
- Guideline #3 (Transcatheter Pulmonary Valve Replacement) - Added applicable coverage guidelines (new to policy).

V. ATTACHMENT

<table>
<thead>
<tr>
<th>LCD ID</th>
<th>LCD Title</th>
<th>Contractor Type</th>
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<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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<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>
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End of Attachment A