Coverage Summary

Transcatheter Heart Valve Procedures

Policy Number: T-007 | Products: UnitedHealthcare Medicare Advantage Plans | Original Approval Date: 06/18/2012
Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee | Last Review Date: 07/23/2019

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)

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.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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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 NCD for Transcatheter Aortic Valve Replacement (TAVR) (20.32).

Note: On June 21, 2019, the Centers for Medicare & Medicaid Services (CMS) issued a final decision memo which will update the coverage criteria for hospitals and physicians for TAVR program. See the Final Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R). (Accessed July 16, 2019)

Local Coverage Determinations (LCDs) do not at this time. (Accessed May 30, 2019)

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 30, 2019)

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 May 30, 2019)

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. (Accessed May 30, 2019)


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 Commercial 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 18, 2019

Accessed September 5, 2019

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 30, 2019)
• Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. (Accessed September 5, 2019)
• All Medicare approved registries will be listed on the CED website located at https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html. (Accessed May 30, 2019)
• For payment rules for NCDs requiring CED, see the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials.

II. DEFINITIONS

III. REFERENCES

See above

IV. REVISION HISTORY

07/23/2019 Guideline 1 [Transcatheter Aortic Valve Replacement (TAVR)]
• Updated coverage criteria for hospital and physicians TAVR program; added reference link to the Centers for Medicare & Medicaid Services (CMS) Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430R) dated June 21, 2019

V. ATTACHMENT

Attachment A - LCD Availability Grid

<table>
<thead>
<tr>
<th>Transcatheter Pulmonary Valve Replacement</th>
</tr>
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<tbody>
<tr>
<td>(CPT code 33477)</td>
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<table>
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</thead>
<tbody>
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<td>Noncovered Services</td>
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<td>First Coast Service Options, Inc.</td>
<td>FL, PR, VI</td>
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<td>A and B MAC</td>
<td>Novitas Solutions, Inc.</td>
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</tr>
</tbody>
</table>

End of Attachment A