Coverage Summary

Transcatheter Heart Valve Procedures

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

Last Review Date: 10/20/2020

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.

COVID-19 Public Health Emergency Waivers & Flexibilities: In response to the COVID-19 Public Health Emergency, CMS has updated some guidance for certain heart valve procedures. For details, see the following Coronavirus Waivers/Flexibilities: Physicians and Other Practitioners (PDF).

For a comprehensive list of Coronavirus Waivers & Flexibilities, refer to https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-
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).** (Accessed June 2, 2020)
   - **Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not at this time.** (Accessed June 2, 2020)
   - **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](https://www.ncdr.com/TVT/Private/Resources/ParticipantDirectory.aspx) or contact the TVT Registry Service Center at (800) 257-4737.** (Accessed June 2, 2020)
   - **For payment rules for NCDs requiring CED, see the UnitedHealthcare Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials.**

2. **Transcatheter Mitral Valve Repair (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 2, 2020)**
   - **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](http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx).**
   - **For payment rules for NCDs requiring CED, see the UnitedHealthcare 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) do not exist.**
   - **For coverage guidelines, refer to the UnitedHealthcare Commercial Medical Policy for Transcatheter Heart Valve Procedures.** (IMPORTANT NOTE: After searching the Medicare Coverage Database, if no LCD/LCA is found, then use the above referenced policy.)
   - **Committee approval date: July 21, 2020**
   - **Accessed July 14, 2020**
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) when coverage criteria are met.

- See the NCD for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34). (Accessed June 2, 2020)
- 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.
- 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 June 2, 2020)
- For payment rules for NCDs requiring CED, see the UnitedHealthcare Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials.

II. DEFINITIONS

III. REFERENCES

IV. REVISION HISTORY
10/20/2020 Coverage Statement
- Added notation pertaining to COVID-19 Public Health Emergency Waivers & Flexibilities to indicate:
  - In response to the COVID-19 Public Health Emergency, the Centers for Medicare & Medicaid (CMS) has updated some guidance for certain heart valve procedures; for details, see the Coronavirus Waivers & Flexibilities: Physicians and Other Practitioners