Coverage Summary

Transcatheter Heart Valve Procedures

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<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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<td>Approved by:</td>
<td>UnitedHealthcare Medicare Benefit Interpretation Committee</td>
<td>Last Review Date:</td>
<td>02/16/2021</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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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-
emergencies/coronavirus-waivers.

(Accessed October 12, 2020)

**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.
   - 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](https://www.cms.gov/Medicare/Coverage/Coverage-Determinations/NCDs) for coverage guidelines on Category B devices.
   - To view the list of current Transcatheter Valve Therapy (TVP) Registry participants, go to [https://www.ncdr.com/TVP/Private/Resources/ParticipantDirectory.aspx](https://www.ncdr.com/TVP/Private/Resources/ParticipantDirectory.aspx) or contact the TVP 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](https://www.cms.gov/Medicare/Coverage/Coverage-Determinations/NCDs).

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)](https://www.cms.gov/Medicare/Coverage/Coverage-Determinations/NCDs) [Note: CMS issued a decision memo on January 19, 2021 replacing the term Transcatheter Mitral Valve Repair (TMVR) with mitral valve Transcatheter Edge-to-Edge Repair (TEER) to more precisely define the treatment addressed in this NCD, which is applicable to TEER for the treatment of functional mitral regurgitation (MR) and degenerative MR. For the detailed updated language, see the proposed final NCD for Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (20.33) and decision memo at [https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=297&type=Open&bc=AAgAAAAACAAA&](https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=297&type=Open&bc=AAgAAAAACAAA&)]. (Accessed February 2, 2021)
   - 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](https://www.cms.gov/Medicare/Coverage/Coverage-Determinations/NCDs).
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 (LAA) (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

02/16/2021 Guideline 2 [Transcatheter Mitral Valve Repair (MitraClip®)]
   • Added language to indicate:
     o Effective Jan. 19, 2021, the Centers for Medicare & Medicaid Services (CMS) issued a decision memo replacing the term “Transcatheter Mitral Valve Repair (TMVR)” with mitral valve “Transcatheter Edge-to-Edge Repair (TEER)” to more precisely define the treatment addressed in the National Coverage Determination (NCD), which is applicable to TEER for the treatment of functional mitral regurgitation (MR) and degenerative MR
     o For the detailed updated language, see the proposed final NCD for Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (20.33) and decision memo at https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=297