

Transcatheter Heart Valve Procedures

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[Instructions for Use](#)

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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)/Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (NCD 20.33)

Coverage Guidelines

Transcatheter heart valve replacement may be covered when Medicare coverage criteria are met.

COVID-19 Public Health Emergency Waivers and Flexibilities: In response to the COVID-19 Public Health Emergency, CMS has updated some guidance for certain heart valve procedures. For a comprehensive list of coronavirus waivers and flexibilities, refer to <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>. (Accessed June 2, 2021)

Transcatheter Aortic Valve Replacement (TAVR)

Medicare covers transcatheter aortic valve replacement (TAVR) under coverage with evidence development (CED) when criteria are met.

- Refer to the [National Coverage Determination \(NCD\) for Transcatheter Aortic Valve Replacement \(TAVR\) \(20.32\)](#). (Accessed June 2, 2021)
- 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 titled [Experimental Procedures and Items, Investigational Devices and Clinical Trials](#) for coverage guidelines on Category B devices.
- The list TAVR Medicare approved clinical trials is available at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR.html>. (Accessed June 2, 2021)
- 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 2, 2021)
- For payment rules for NCDs requiring CED, refer to the UnitedHealthcare Coverage Summary titled [Experimental Procedures and Items, Investigational Devices and Clinical Trials](#).

Transcatheter Mitral Valve Repair (MitraClip®)

The Centers for Medicare and 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 \(TMVR\) \(20.33\)](#).
- 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, refer to 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=273>. (Accessed June 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>. (Accessed June 2, 2021)
- The list of Medicare approved clinical trials is available at <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TMVR.html>. (Accessed June 2, 2021)
- For payment rules for NCDs requiring CED, refer to the UnitedHealthcare Coverage Summary titled [Experimental Procedures and Items, Investigational Devices and Clinical Trials](#).

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 titled [Transcatheter Heart Valve Procedures](#).

Note: After searching the [Medicare Coverage Database](#), if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CPT code 33340)

The Centers for Medicare and 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.

- Refer to the [NCD for Percutaneous Left Atrial Appendage Closure \(LAAC\) \(20.34\)](#). (Accessed June 2, 2021)
- 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, 2021)
- For payment rules for NCDs requiring CED, refer to the UnitedHealthcare Coverage Summary titled [Experimental Procedures and Items, Investigational Devices and Clinical Trials](#).

Policy History/Revision Information

Date	Summary of Changes
06/14/2021	<p>Coverage Guidelines</p> <p>Coverage Statement</p> <ul style="list-style-type: none"> • Updated notation pertaining to COVID-19 Public Health Emergency Waivers & Flexibilities; removed reference link to the waiver titled <i>Physicians and Other Practitioners</i> <p>Transcatheter Aortic Valve Replacement (TAVR)</p> <ul style="list-style-type: none"> • Removed notation affirming the nonexistence of Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) <p>Percutaneous Left Atrial Appendage (LAA) Closure Therapy (CPT code 33340)</p> <ul style="list-style-type: none"> • Removed language indicating LCDs/LCAs exist and compliance with these policies is required where applicable <p>Supporting Information</p> <p>Archived previous policy version MCS094.01</p>

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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 are 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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