Medicare Medical Policy

Tricuspid Transcatheter Edge-to-Edge Repair (T-TEER)

MEDICARE MEDICAL POLICY NUMBER: 442

Effective Date: 8/1/2025

Last Review Date: 7/2025

Next Annual Review: 7/2026

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Notes: Tricuspid valve repair procedures and devices are different from tricuspid valve replacement systems. Tricuspid valve ***repair*** systems are addressed in this policy, while tricuspid valve ***replacement*** systems (0646T) are addressed in a separate Medicare medical policy.

Service	Medicare Guidelines
Tricuspid Transcatheter Edge-to-Edge Repair (T-TEER)	CMS Final Decision Memo for Transcatheter Tricuspid Valve Replacement (TTVR) (CAG-00468N) **NOTES:** • On July 2, 2025, Medicare published a Final Decision Memo to provide coverage criteria for T-TEER for symptomatic tricuspid regurgitation (TR). An NCD will be formally developed in the future, and the effective date will be retroactive back to the date of this decision memo; however, until the NCD is finalized, this decision memo can be used for Medicare coverage decision-making. • This coverage criteria provides coverage in the context of the coverage with evidence development (CED) studies. Medicare-approved registries and clinical trials can be found on the Medicare CED website. *When a list of Medicare approved studies is available for tricuspid TEER (current TEER link is for the mitral valve), an updated link will be added to this policy.* • According to the CMS Decision Memo, "Nothing in this NCD would preclude coverage of T-TEER through… the Investigational Device Exemption (IDE) Policy." Therefore, MA plan coverage of these services may **also** be available if rendered in the context of a Medicare approved IDE study • The Abbott TriClip System is the first FDA cleared tricuspid transcatheter edge-to-edge repair (T-TEER) device in the U.S. *(CAG-00468N)*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is

uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Transcatheter Tricuspid Valve Replacement (TTVR), MP433

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to review for medical necessity, the following documentation **must** be provided. If any of these items are not submitted, the review may be delayed and the decision outcome could be affected:

- All clinical documentation pertinent to request, including:
  - Condition to be treated;
  - Documentation of all specialists involved in the heart team who have examined the patient's suitability for valve replacement and the rationale for their judgment (the criteria provide specific requirements regarding which specialists are to examine the patient – these requirements will be used as appropriate for the request); and
  - Confirmation the patient is under the care of a heart team and that all specialists in the heart team have experience in the care and treatment of tricuspid regurgitation;
- The name of the device that will be used; and,
- The NCT number for the registry or study the member or provider is enrolled in (enrollment is a requirement under the Medicare criteria).

BACKGROUND

"Tricuspid regurgitation (TR) is a cardiac condition that occurs when the tricuspid valve (TV) between the right atrium (RA) and right ventricle (RV) does not function properly, allowing blood to flow backwards from the RV to the RA. TR is historically classified as either primary or secondary based on its etiology… A minimally-invasive, percutaneous, transvenous, catheter-based approach to TV repair has emerged as a potential treatment for TR." *(CAG-00468N)*

On July 2, 2025, Medicare published a Final Decision Memo to detail coverage criteria for tricuspid transcatheter edge-to-edge repair (T-TEER) for symptomatic tricuspid regurgitation (TR).

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment

policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

Transcatheter Tricuspid Valve Devices

On April 1, 2024, the FDA approved the TriClip G4 System premarket approval (PMA) application (P230007). This device is indicated for improving quality of life (QoL) and functional status in patients with symptomatic severe TR despite optimal medical therapy (OMT), who are at intermediate or greater risk for surgery and in whom TEER is clinically appropriate and is expected to reduce TR severity to moderate or less, as determined by a multidisciplinary heart team.

The Abbott TriClip System is the first FDA cleared tricuspid transcatheter edge-to-edge repair (T-TEER) device in the U.S. *(CAG-00468N)*

BILLING GUIDELINES AND CODING

CODES*		
CPT	0569T	Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis
	0570T	Transcatheter tricuspid valve repair, percutaneous approach; each additional prosthesis during same session (List separately in addition to code for primary procedure)
HCPCS	None	

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
8/2025	New Medicare Advantage medical policy