

Medicare Medical Policy

Transcatheter Tricuspid Valve Replacement (TTVR)

MEDICARE MEDICAL POLICY NUMBER: 433

Effective Date: 5/1/2025	MEDICARE COVERAGE CRITERIA	2
Last Review Date: 4/2025	POLICY CROSS REFERENCES.....	2
Next Annual Review: 4/2026	POLICY GUIDELINES.....	3
	REGULATORY STATUS.....	3
	BILLING GUIDELINES AND CODING	4
	REFERENCES.....	4
	POLICY REVISION HISTORY.....	4

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 **replacement** systems are addressed in this policy, while tricuspid valve **repair** systems (0569T, 0570T) are addressed in a separate Medicare medical policy.

Service	Medicare Guidelines
Transcatheter Tricuspid Valve Replacement (TTVR)	<p>CMS Final Decision Memo for Transcatheter Tricuspid Valve Replacement (TTVR) (CAG-00467N)</p> <p>NOTES:</p> <ul style="list-style-type: none">On March 19, 2025, Medicare published a Final Decision Memo to provide coverage criteria for TTVR 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 Transcatheter Tricuspid Valve Replacement (TTVR) web page.The Edwards Lifesciences EVOQUE system is the first FDA cleared transcatheter TV replacement device in the US. (CAG-00467N)

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

None

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, approach to TV replacement has emerged as a potential treatment for TR.” (CAG-00467N)

On March 19, 2025, Medicare published a Final Decision Memo to detail coverage criteria for transcatheter tricuspid valve replacement (TTVR) 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.

Tricuspid Valve Replacement Systems

On February 1, 2024, the FDA approved the Edwards EVOQUE Tricuspid Valve Replacement System (EVOQUE system) premarket approval (PMA) application (P230013). The device is indicated for the

improvement of health status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, for whom tricuspid valve replacement is deemed appropriate by a heart team.

The Edwards Lifesciences EVOQUE system is the first FDA cleared transcatheter TV replacement device in the US. (CAG-00467N)

BILLING GUIDELINES AND CODING

CODES*		
CPT	0646T	Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed
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
5/2025	New Medicare Advantage medical policy