

TriClip™ Transcatheter Edge-to-Edge Repair (TEER) System

Medicare Coverage with Evidence Development Study Information: Professional

This document summarizes the Centers for Medicare & Medicaid Services (CMS) billing requirements for traditional Medicare and Medicare Advantage patients for the TriClip™ TEER System, which is covered by a National Coverage Determination (NCD) under Coverage with Evidence Development (CED). It is the physician's responsibility to determine appropriate coding for a particular patient and/or procedure. Any claim should be coded appropriately and supported with adequate documentation in the medical record.

CODES/MODIFIERS/OTHERS	CMS REQUIREMENT
DIAGNOSIS CODES	
Applicable primary diagnosis codes	Yes, in all cases
Z00.6*: Encounter for examination for normal comparison and control in clinical research program	Yes, in all cases
Applicable secondary diagnosis codes	If applicable
CPT [‡] CODES	
0569T: Transcatheter tricuspid valve repair percutaneous approach	Yes, in all cases
+0570T: Transcatheter tricuspid valve repair percutaneous approach. Additional prosthesis during same session (List separately in addition to code for primary procedure). (Use +0570T in conjunction with 0569T)	If applicable
CPT [‡] MODIFIERS	
-Q0: Investigational/Routine clinical service provided in a clinical research study that is in an approved clinical research study.	Yes, in all cases
-62: Use for physician claims for cases where two surgeons/co-surgeons perform TEER. Note that in scenarios where co-surgeon participation is medically necessary, the submission of supporting documentation is required.	If applicable
-80/-82: Use for assistant surgeon claims for TEER. Append modifier to assistant surgeon claims; do not append modifier to primary surgeon claims. Use -80 when TEER is performed at non-teaching community hospitals without surgery residents. Use -82 for when TEER is performed at teaching hospitals with surgery residents; -82 indicates qualified surgery resident unavailable. Documentation regarding medical necessity required.	If applicable
NCT NUMBER	
06920745*	Yes, in all cases

^{*}These are requirements because of the CED

SAMPLE PROFESSIONAL CLAIM FORM

TriClip™ TEER Crosswalk Example FOR ILLUSTRATIVE PURPOSES ONLY HEALTH INSURANCE CLAIM FORM APPROVED BY NATIONAL UNIFORM GLAIM COMMITTEE (NUCC) 02/12					
HEALTH INSURANCE CLAIM FORM APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12				PICA FTTT	
	ALTH PLAN BLK LUNG	THER	1a. INSURED'S I.D. NUMBER (For	r Program in Item 1)	
PATIENT'S NAME (Last Name, First Name, Middle Initial) S. PATIEN Middle Initial) S. PATIEN Middle Initial)	T'S BIRTH DATE SEX DD YY M F		4. INSURED'S NAME (Last Name, First Name, Middle	e Initial)	
Self	T RELATIONSHIP TO INSURED Spouse Child Other		7. INSURED'S ADDRESS (No., Street)		
CITY STATE 8. RESER	VED FOR NUCC USE		CITY	STATE	
Item number 19 is used to report additional claim informallows for the entry of 71 characters. Due to this limitati information is also entered into the Line Notes for Box 2	on, the crosswalk	8	ZIP CODE TELEPHONE (Ind () 11. INSURED'S POLICY GROUP OR FECA NUMBER	ORM	
a Example: Your physician will report CPT code 33418 as t for CPT 0569T and CPT code 33419 as the crosswalk cod	he crosswalk code		a. INSURED'S DATE OF BIRTH	SEX FI	
example of the entry may be reflected as NTEADDPerc Transcatheter Tricuspid Valve Repair CPT 0569T crosswalk to 33418			b. OTHER CLAIM ID (Designated by NUCC) C. INSURANCE PLAN NAME OR PROGRAM NAME		
No punctuation at the end and no space between the N prefix.	FEADD qualifier		d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO #yes, complete ifer	NO. 107 MONEY	
Additionally, item number 19 is used to report Prior Aut	it	ary	INSURED'S OR AUTHORIZED PERSON'S SIGN payment of medical benefits to the undersigned phaser wices described below.	ATURE I authorize	
If your physician would like to provide detail that cannot number 19 due to character limitation, submission of an	attachment is	_	For paper claims, the eight- digit NCT number is	NT COCHRATION	
permitted. Please refer to the most current instructions from the payer and NUCC.		_	reported with the prefix of	ENT OCCUPATION A	
17. NAME OF REPERHING PROVIDER OF OTHER SOURCE 174.			CT. For electronic claims,		
19. ADDITIONAL CLAIM INFORMATION (Designated by VCC)			the eight-digit NCT number		
NTEADDPerc Transcatheter Tricuspid Valve Repair CPT 0569T crosswalk to 33418 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (245)			is reported with no prefix.		
21. DIAGNOSIS CH NATURE OF ILLINESS CH INJURY HEIGHT AL ID SET MOS IIND GROW (24E) ICD Ind. CODE CHIGINAL HEF- NO.			0.		
EL FL GL HL			23. PRIOR AN HORIZATION NUMBER:		
			CT06920745		
From To FLACEOF (Explain Unusual of MM DD YY MM DD YY SERVICE EMG CPT/HCPCS			F. G. H. I. DAYS EPROT ID. SCHARGES UNITS PRO	RENDERING PROVIDER IN F	
ZZNOC TRICUSPID TEER PX WITH IMPLANT CROSSWALK 0569T TO 33	1 1 1 1		999999 00 The char	rges	
XX XX XX XX XX XX 21 0569T Q ZZNOC TRICUSPID TEER PX ADDITIONAL PROSTHESIS CROSSWALK			reported		
XX XX XX XX XX XX 21 0570T Q	0		addada nn	able to the	
3 1 1	1 1 1 1	ĺ	AND THE RESIDENCE OF THE PARTY	reported for	
			the sele	cted 💆	
Item number 24 Line Notes (shaded section) is used t	o report supplemental	1	crosswa	reported for cted alk CPT [‡] code	
information related to the completed service line dire	ctly underneath it.		Example	e: Your	
This field allows for the entry of 61 characters.			n charges		
25. Example: Your physician will report CPT code 33418 as the crosswalk code		?		or CPT [‡] code	
for CPT 0569T. The entry may be reflected as ZZNOC TRICUSPID TEER PX 31. S WITH IMPLANT CROSSWALK 0569T TO 33418 33. BIL			\$ \$ 33418.		
No punctuation at the end and no space between the prefix.	ZZNOC qualifier				
NUCC Instruction Manual available at: www.nucc.org	EASE PRINT OR TYPE		a. APPROVED OMB-0938-1197		

Important Safety Information

TRICLIP™ G5 SYSTEM

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Rx Only

Indications and Usage: The $TriClip^{TM}$ G5 System is indicated for improving quality of life and functional status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, who are at intermediate or greater risk for surgery and in whom transcatheter edge-to-edge valve repair is clinically appropriate and is expected to reduce tricuspid regurgitation severity to moderate or less, as determined by a multidisciplinary heart team.

Contraindications: The TriClip™ G₅ System is contraindicated for use in patients with the following conditions: Intolerance, including allergy or untreatable hypersensitivity, to procedural anticoagulation; Untreatable hypersensitivity to Implant components (nickel-titanium alloy, cobalt-chromium alloy); Active endocarditis or other active infection of the tricuspid valve.

Potential Adverse Events: The following events have been identified as possible complications of the TriClip™ G5 Procedure. Allergic reactions or hypersensitivity to latex, contrast agent, anesthesia, device materials and drug reactions to anticoagulation, or antiplatelet drugs; Additional treatment / surgery from device-related complications; Bleeding; Blood disorders (including coagulopathy, hemolysis, and Heparin Induced Thrombocytopenia (HIT)); Cardiac arrhythmias (including conduction disorders, atrial arrhythmias, ventricular arrhythmias); Cardiac ischemic conditions (including myocardial infarction, myocardial ischemia, unstable angina, and stable angina); Cardiac perforation; Cardiac tamponade; Chest pain; Death; Dyspnea; Edema; Embolization (device or components of the device); Endocarditis; Fever or hyperthermia; Fluoroscopy and Transesophageal echocardiogram (TEE) -related complications; Skin injury or tissue changes due to exposure to ionizing radiation, Esophageal irritation, Esophageal perforation, Gastrointestinal bleeding; Hypotension / hypertension; Infection including: Septicemia; Nausea or vomiting; Pain; Pericardial effusion; Stroke / cerebrovascular accident (CVA) and transient ischemic attack (TIA); System organ failure: Cardio-respiratory arrest, Worsening heart failure, Pulmonary congestion, Respiratory dysfunction or failure or atelectasis, Renal insufficiency or failure, Shock (including cardiogenic and anaphylactic); Thrombosis; Tricuspid valve complications, which may complicate or prevent later surgical repair, including: Chordal entanglement / rupture, Single leaflet device attachment (SLDA), Dislodgement of previously implanted devices, Tissue damage, Tricuspid valve stenosis, Worsening, persistent or residual regurgitation; Vascular access complications which may require additional intervention, including: Wound dehiscence, Bleeding of the access site, Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation (rupture), vascular occlusion, Embolism (air, thrombus), Peripheral nerve injury; Venous thrombosis (including deep vein thrombosis) and thromboembolism (including pulmonary embolism).

References:

- National Coverage Determination TriClip: <u>NCA Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER) (CAG-00468N) Decision Memo</u>
- · 2025 ICD-10-PCS: https://www.cms.gov/files/document/2025-official-icd-10-pcs-coding-guidelines.pdf
- · 2025 ICD-10-CM: https://www.cms.gov/files/document/fy-2025-icd-10-cm-coding-guidelines.pdf
- Coverage with Evidence Development: https://www.cms.gov/medicare/coverage/evidence
- CMS MLN Matters MM8401 Mandatory Reporting of 8-Digit Clinical Trial Number on Claims: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/MM8401.pdf
- CPT* Copyright 2025 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association: https://www.ama-assn.org/
- Physician Prospective Payment Final rule with comment period and final CY2025 Payment Rates. CMS-1807-F: https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices/cms-1807-f
- National Correct Coding Initiative Edits: https://www.cms.gov/medicare/coding-billing/ncci-medicare
- Medicare Claims Processing Manual Chapter 32: Medicare Claims Processing Manual (cms.gov)
- CMS UB-04 Form: https://api-prod.palmettogba.com/h/elearn/ub04/story.html
- CMS-1500 Paper Form: https://api-prod.palmettogba.com/h/elearn/interactivecms1500/story.html
- D4 Value Code for Institutional Claim Form UB-04: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm5790.pdf

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