Abbott

HEALTH ECONOMICS & REIMBURSEMENT

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

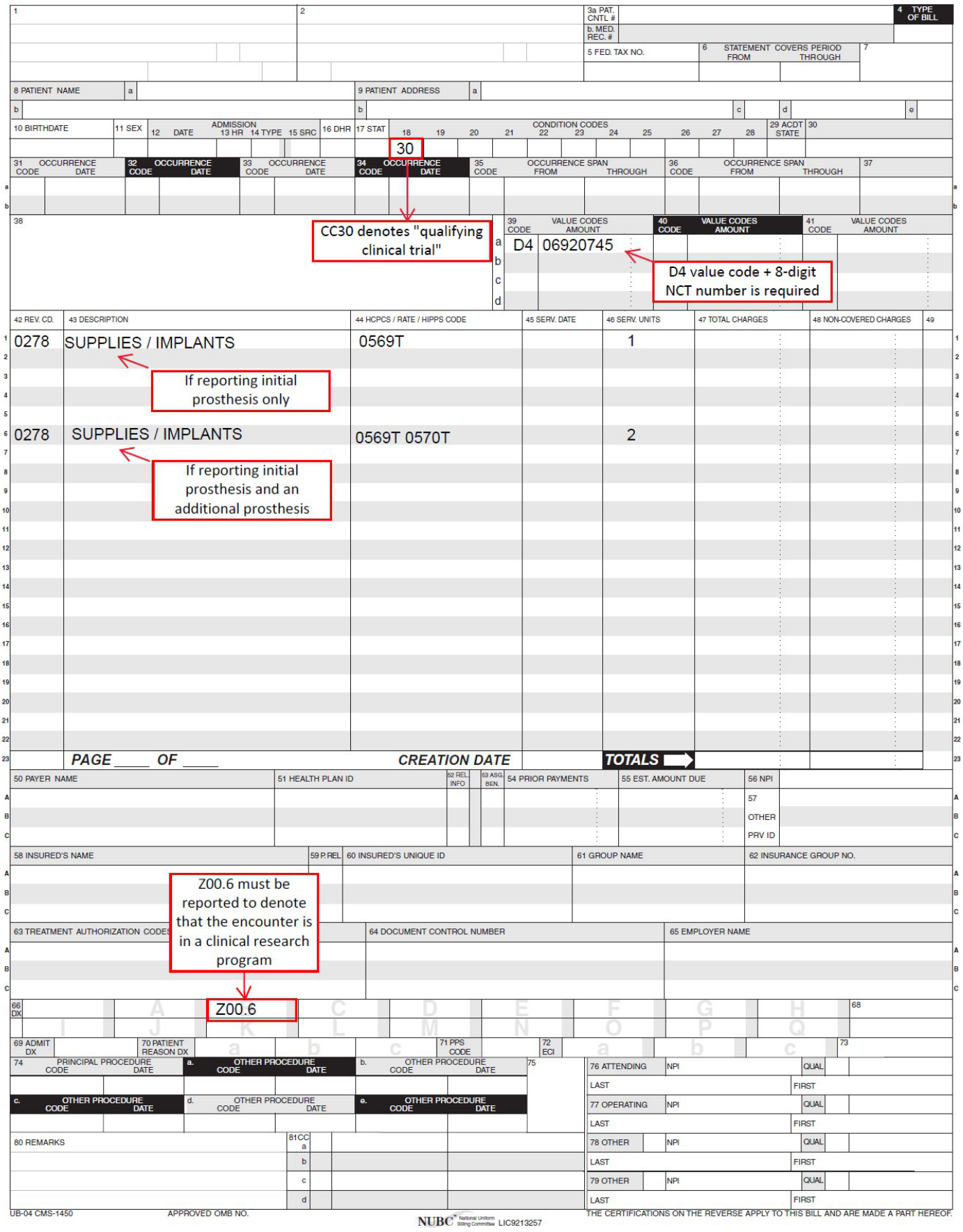
Medicare Coverage with Evidence Development Study Information: Institutional

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
ICD-10-PCS CODE	
02UJ3JZ: Supplement tricuspid valve with Synthetic Substitute, Percutaneous approach	Yes, in all cases
CONDITION CODE	
30*: qualifying clinical trial	Yes, in all cases
NCT NUMBER	
06920745*	Yes, in all cases
VALUE CODE	
D4*	Yes, in all cases

*These codes are unique requirements because of the CED.

SAMPLE INSTITUTIONAL CLAIM FORM



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™ 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: NCA - Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER) (CAG-00468N) - Decision Memo
- CMS FY2025 Hospital Inpatient Prospective Payment-Final Rule Home Page CMS-1808-F: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-ipps-final-rule-home-page
- 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/
- 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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