Coverage with Evidence Development Approval Letter
TriClip™ Transcatheter Edge-to-Edge Repair (TEER) System

The following document may be submitted to Medicare or Medicare Advantage Plans for:

- Prior authorization
- Prior authorization appeals, or
- Post-service denials, when appropriate.

Abbott has a team of skilled specialists to answer your TriClip reimbursement questions. Please reach out to them directly by emailing AbbottEconomics@abbott.com.

Do not include this instruction page in your submission.

Important Safety Information

The TriClip™ G5 System

Rx Only
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.

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).

CAUTION: Product(s) intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at www.eifu.abbott for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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Center for Clinical Standards and Quality
Coverage and Analysis Group

Elizabeth Thoma
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Structural Heart
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July 8, 2025

Dear Ms. Thoma:

Thank you for your study protocol submission and request for coverage under Coverage with Evidence Development (CED) for Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER). After careful review by our multidisciplinary team of your proposed CED study, "TRIClip CoverAge with Evidence Development (CED) Real-World Evidence (RWE) Study (TRICARE)" (NCT06920745), the Centers for Medicare & Medicaid Services (CMS) has determined that it fulfills the requirements of the T-TEER National Coverage Determination (NCD).

You must notify us of any substantial changes to the protocol, such as sample size revisions or modifications of the analysis methodology. The ClinicalTrials.gov website must be kept up to date. Please remember that the results of your research should be published in peer-reviewed journals. We may use these results in future coverage decisions.

To facilitate the Medicare payment process, you should provide your study sites with appropriate billing instructions. These include entering the National Clinical Trial (NCT) identifier from the ClinicalTrials.gov website on Medicare claims along with the other codes and modifiers provided in the NCD claims processing instructions.

We appreciate your commitment to research and evidentiary development to improve care for Medicare beneficiaries. Please direct any questions to Nina Arya at Nina.Arya@cms.hhs.gov

Sincerely,

Tamara S. Jensen -S
X

Digitally signed by Tamara S. Jensen -S
Date: 2025.07.08 13:31:36 -04'00'

Tamara Syrek Jensen, JD
Director, Coverage and Analysis Group