FREQUENTLY ASKED QUESTIONS (FAQ)

Tricuspid Transcatheter Edge-to-Edge Repair (T-TEER) for Tricuspid Valve Regurgitation National Coverage Determination (NCD) including the TriClip™ TEER System

GENERAL QUESTIONS

1) What is a National Coverage Determination?

A National Coverage Determination (NCD) is a Medicare policy that covers a specific medical item or service nationally. CMS has issued the NCD for **Tricuspid Transcatheter Edge-to-Edge Repair (T-TEER) for Tricuspid Valve Regurgitation** including the TriClip™ TEER System under Coverage with Evidence Determination (CED).

2) What is Coverage with Evidence Development (CED)?

Coverage with Evidence Development (CED) is a coverage pathway where Medicare covers items and services on the condition that they are provided in the context of an approved clinical study. CED provides coverage for Medicare beneficiaries while the evidence is developed.

The TriClip CED Real-World Evidence Study (TRICARE) is an observational study that will leverage real-world data collected through routine delivery of healthcare in the United States. The study is a prospectively-designed retrospective data analysis, and will not influence the care a patient receives during routine interactions with their healthcare providers. Abbott has requested and been granted a waiver of informed consent and a HIPAA waiver from Western IRB for the TRICARE study.

3) What is the significance of the NCD for the TriClip™ TEER System?

The T-TEER NCD provides coverage for the TriClip™ TEER System in treating patients with symptomatic severe tricuspid valve regurgitation as determined appropriate by a heart team and when NCD criteria are met. The T-TEER NCD provides coverage for all Medicare beneficiaries, including both Medicare Fee-For-Service and Medicare Advantage patients.

CED & CLINICAL TRIAL QUESTIONS

1) What is a National Clinical Trial (NCT) number, and why is it important for the TriClip™ TEER System CED study?

A National Clinical Trial (NCT) number is a unique identifier that enables reporting for the CED study. The NCT number and other clinical trial codes and modifiers must be reported on all claim forms to be considered for coverage. The NCT number for the approved TriClip CED Real-World Evidence Study (TRICARE) is 06920745. Please refer to the Transcatheter Edge-to-Edge Repair Coding Guide on our website for more information.

2) Will other T-TEER devices require their own CED study or registry?

Yes. Other T-TEER devices will need their own approved CED study for coverage under the NCD. The TRICARE study is specific to the TriClip™ TEER System.

3) Am I required to enter patients into the TVT Registry?

Please continue to enter patients into the TVT Registry. Data collection via the TVT Registry is a post-approval condition set by the FDA. While not tied to reimbursement, the TVT Registry plays a critical role in post-approval surveillance and clinical research and has a role in the CED study protocol. Complete and accurate data entry supports safety monitoring and real-world evidence collection for procedures like T-TEER.

4) What can I do to enroll my patient in the CED study?

The TriClip CED RWE study (TRICARE) is a real-world evidence study using retrospective data and does not require case form completion or data entry. The TriClip CED RWE study (TRICARE) NCT number 06920745 and clinical trial code information below are the only requirements for reimbursement. The TRICARE protocol, approved by CMS, utilizes information reported on hospital billing claims to identify patients and complete the pre-specified analysis plan per the approved CED Study protocol.

Facilities will be required to add the following to their claim forms:

- NCT number 06920745
- Z00.6 diagnosis code
- Condition code 30

Physicians will be required to add the following to their claim forms:

- NCT number 06920745
- Z00.6 diagnosis code
- -Q0 modifier

IMPACT ON PRACTICES AND PATIENTS

1) Does the NCD with CED impact physician coding?

The T-TEER NCD with CED impacts patient coverage. Physicians still report codes 0569T and +0570T on their claims. In addition, physician claims should include the NCT number 06920745, diagnosis code Z00.6, and modifier -Q0.

2) How do I enroll patients in the CED Study while Medicare Advantage plans are updating their policies and systems?

CMS approved the TriClip CED RWE study (TRICARE) protocol; therefore, the NCD is effective for the TriClip™ TEER System. Implanting sites and physicians may consider using the TriClip TEER Prior Authorization checklist and submit copies of the TRICARE approval letter and NCT number 06920745 with each prior authorization and appeal.

Also consider using the Abbott Patient Therapy Access (PTA) support for prior authorizations and appeals at TriClip_pta@abbott.com or (877) 706-7246.

Note: The PTA team is unable to assist with external appeals.

3) What should practices do about patients who were previously denied?

Practices can review the NCD criteria to determine if patients may now qualify for TriClip™ therapy under the coverage criteria.

4) What are the key patient selection criteria under the NCD?

Refer to the CMS website to read more about the Patient Criteria (I.B.1) and Physician Criteria (I.B.2) for tricuspid transcatheter edge-to-edge repair (T-TEER) NCD including the TriClip™ TEER System.

5) What happens if a Medicare beneficiary under Traditional or Medicare Advantage plan is not enrolled in the CED study?

The TriClip CED RWE study (TRICARE) NCT number 06920745 is only required in connection with claims for Medicare beneficiaries, including Fee-For-Service and Medicare Advantage. Medicare requires enrollment in an approved CED study to qualify for coverage. Private payors and Medicaid are not under the scope of the NCD and therefore do not require CED study information be reported on the claim.

6) Will commercial payors follow the NCD criteria?

Many commercial payors tend to follow CMS decisions and may eventually adopt similar policies. Practices will need to check with individual payors for updates.

ADDITIONAL RESOURCES

1) Where can I find more information about the NCD?

Read more about the tricuspid transcatheter edge-to-edge repair (T-TEER) NCD including the TriClip™ TEER System at the CMS website.

2) What if I have questions that aren't answered in this FAQ?

Please reach out to the HE&R team at Abbott that can be contacted at the email: AbbottEconomics@abbott.com.

References

- NCD Final Decision Memo: NCA - Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER) (CAG-00468N) - Decision Memo
- TriClip CED RWE Study: https://www.cms.gov/medicare/coverage/coverage-evidence-development/transcatheter-edge-edge-repair-tricuspid-valve-regurgitation-t-teer
- Coverage with Evidence Development: https://www.cms.gov/medicare/coverage/evidence
- Medicare Coverage Determination Process: https://www.cms.gov/medicare/coverage/determination-process
- NCT: https://clinicaltrials.gov/study/NCT06920745

Important Safety Information

The 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).

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