**SAMPLE APPEAL TEMPLATE**

**Prior Authorization Denial, Pre-procedural Appeal**

**Transcatheter Tricuspid Valve Repair (TTVr) Or Tricuspid Transcatheter Edge-to-Edge Repair (Tricuspid TEER)\***

**Instructions for completing the sample appeal letter:**

1. Please **customize** the appeal letter template based on the medical appropriateness of Tricuspid Transcatheter Edge-to-Edge Repair (Tricuspid TEER) for your patient. Any information added is at the discretion of the treating physician or the care team. Fields required for customization are **highlighted in yellow**.
2. It is important to provide the most complete information and documentation to assist with the appeal of a prior authorization denial. Some useful supporting documents are considered:
   1. Patient’s medical records supporting the tricuspid regurgitation diagnosis, severity, clinical presentations, and symptoms.
   2. List all the physicians including the cardiac surgeon who have examined the patient and recommended TriClip™ therapy.
   3. TriClip™ G4 System FDA approval letter(s).
   4. An appendix bibliography demonstrating the widespread acceptance of TTVr or Tricuspid TEER.
3. After you have customized the appeal letter, please make sure to delete any specific instructions for completion that are highlighted throughout the letter, so the health plan does not misinterpret the information.

*\*Refer to the Important Safety Information on page 2.*

***PLEASE REMOVE THIS PAGE BEFORE SUBMITTING THE LETTER TO THE PAYER.***

**Rx Only**

**Important Safety Information**

**TRICLIP™ G4 SYSTEM**

**Indications**

The TriClip™ G4 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 G4 System is contraindicated 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 G4 Procedure. Allergic reactions or hypersensitivity to latex, contrast agent, anaesthesia, 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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***PLEASE REMOVE THIS PAGE BEFORE SUBMITTING THE LETTER TO THE PAYER.***

[Physician Letterhead]

Date: [Month, Day, Year]

Attention: Appeals Department

Reference number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Payer Name

Grievance and Appeals

PO Box XXXXXXX

City, State, Zip Code

FAX: xxx-xxx-xxxx

**Re: Expedited Appeal of Prior Authorization Denial [denial number] for the TriClip™ Transcatheter Edge-to-Edge Repair (TEER) or Transcatheter Tricuspid Valve Repair (TTVr) Using TriClip™ System, requesting review by a Same Specialty Provider (insert provider type)**

Patient Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Policy Holder Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient ID # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Policy, Group, or Claim # \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient’s Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Diagnosis: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Procedure: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

CPT Code: 0569T (Transcatheter tricuspid valve repair percutaneous approach)

Dear **Appeals and Grievances**:

I am writing to request reconsideration of the denial of prior authorization, **[denial #],** for theTriClip Transcatheter Edge-to-Edge Repair (TEER), also known as Transcatheter Tricuspid Valve Repair (TTVr) procedure. The service to be provided is a medically necessary transcatheter tricuspid valve repair due to tricuspid regurgitation. On behalf of your client and our patient, **[patient’s name],** I respectfully request a re-evaluation of your denial of medical coverage.

The procedure will be performed on (**date**), and the denial was received recently, stating only: “***information submitted fails to meet medical necessity criteria****”*. I have attached a copy of the denial letter. I would like to further explore this decision on several fronts. While I understand an insurance company’s need to audit procedures in order to ascertain documentation of medical necessity, I have performed successful TTVr/ Tricuspid TEER for similar patients with improvement of clinical indicators. Based on my real-world experience and careful examination of the patient and medical records, I believe that this patient will benefit from this procedure. [**He/she**] meets the medical criteria outlined for the procedure therefore, the prior authorization should be granted.

My patient, **[patient’s name]**, also met the FDA indication for coverage of tricuspid TEER as described below:

“The TriClip G4 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.”

**Background**

Tricuspid Regurgitation (TR) is defined by the backflow of blood from the right ventricle into the right atrium during systole. TR can be due to anatomical reasons (primary TR) or a result of several other etiologies such as pulmonary hypertension, ischemic heart disease, and cardiomyopathies (secondary TR). TriClip TEER offers a safe and effective alternative option for patients who remain symptomatic despite optimal guideline-directed medical therapy. TriClip Therapy addresses a significant unmet clinical need for patients who otherwise are left to face the dismal prognosis of untreated TR.

On February 13th, 2024, the FDA conducted an advisory panel to further evaluate the safety and efficacy of TriClip Therapy based on the evidence submitted. The panel's decision was based on clinical data from the TRILUMINATE pivotal trial, as well as expert testimony. The panel overwhelmingly backed the safety and effectiveness of the TriClip Therapy through the vote:

* The panel vote confirmed 13 to 1, with 0 abstentions that the **benefits of Abbott's TriClip system** **outweighed the risks** for the treatment of people with tricuspid regurgitation.
* All the 14 panel members voted “yes” to the question: “Is there reasonable assurance that the Abbott **TriClip System is safe** for use in patients who meet the criteria specified in the proposed indication”.
* 12 out of 14 panel experts voted “yes” to the question: “Is there reasonable assurance that the Abbott **TriClip System is effective** for use in the patients who meet the criteria specified in the proposed indication”.

**Clinical Evidence Summary Highlights**

Clinical research has proven the safety and efficacy of the TriClip System based on the TRILUMINATE Pivotal randomized controlled trial (RCT). The TRILUMINATE Pivotal study is a multi-center, prospective, open-label RCT conducted across 65 sites in the US, Canada, and Europe (Sorajja et al., 2023). Patients were randomized 1:1 to receive either Tricuspid TEER using the TriClip System or medical therapy (MT) alone. The primary analysis population included the first 350 randomized patients and included follow-up through 1 year. This RCT met both the primary endpoint and the secondary safety endpoints, demonstrating that the device is safe and effective. The TriClip procedure was very safe with no operative mortality or urgent cardiac surgery for TriClip-related adverse events, and extremely low rates of cardiovascular mortality and new onset renal failure.

The primary endpoint, a hierarchal composite of all-cause mortality or tricuspid valve surgery, heart failure hospitalization, and improvement in quality of life (QoL) measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ) at one year, was met (win ratio [WR]: 1.44, 95% CI: 1.03, 2.08], **p=0.0311**, indicating that Tricuspid TEER with TriClip was **superior** to medical therapy alone.

* In addition to the intention-to-treat analysis above, the sensitivity analysis in the as-treated population was also met with [WR]: 1.55, 95% CI: 1.10 to 2.24 (**P =0.0126**).

Besides the primary endpoint, several other outcomes were captured in this RCT that highlight the safety and effectiveness of TriClip Therapy:

* **Changes in quality of life** were measured via the KCCQ instrument. As noted by Spertus et al 2020, “a change of 5 points is considered to be a small but clinically important change, whereas changes of 10 and 20 points are considered moderate-to-large”.
  + Adjusting for the baseline KCCQ-OS value, the analysis of the covariance model showed a **significantly greater improvement in the Device group** compared to the MT group (12.34 vs. 0.61, **p<0.0001**). The device group had an average increase in KCCQ-OS score of 11.7 more points (95% CI: 6.8 to 16.6) than the MT group from baseline to one year.
* The proportion of patients categorized as New York Heart Association (NYHA) functional class I/II improved from 46% at baseline to 84% at 12 months for the Device group versus 47% to 59% for the Control group, indicating **significant symptomatic benefit** from the device.
* The TriClip device was designed to reduce TR and the RCT demonstrated that the device achieved this purpose: at 30 days, **TR reduction to moderate or less was achieved in 87.0%** of the Device group, vs. only 5.4% of the Control group **(p<0.0001).**
* 98.3% of patients were **free of major adverse events (MAEs)** at 30 days, with no procedural mortality, and very low rates of cardiovascular mortality and renal failure. The MAE-free rate exceeded the performance goal of 90% **(p<0.001).**
* Through 12 months,there was **no device embolization or thrombosis** among patients in the TEER group. The need for new permanent pacemaker implantation was low and comparable between the Device and Control groups through 30 days and 12 months indicating **no increased risk of conduction disturbances** with TriClip therapy.

**Patient’s Clinical History**

As a cardiologist experienced in heart valve diseases, I have determined that the patient requires intervention for **[his/her]** symptomatic severe TR and meets the indicated requirements for TTVr/Tricuspid TEER. **[Patient Name]** has been evaluated by a multidisciplinary heart team who have determined that **[he/she]** requires transcatheter tricuspid valve repair for **[his/her]** symptomatic severe TR.

**[Include the following [multidisciplinary heart team]:**

* **Name and title of cardiac surgeon, how many procedures performed, a report from the surgeon documenting the patient’s risk factors, why the patient is not a good candidate for surgery, and recommendation for TriClip™ therapy.**
* **List all other physicians who have seen the patient and recommend TriClip™ therapy and include reports and findings.]**

My patient is a/an **[age]**-year old **[race] [gender]** who has severe symptomatic TR.

* **[Include a detailed description of the patient’s condition (ability to perform daily activities, overall condition, shortness of breath, edema, ascites, 6-Minute Walking Distance (6MWD), exercise intolerance, etc.).**
* **Provide a diagnostic description and ICD-10-CM diagnosis codes and NYHA class and description].**
* **Describe relevant patient clinical information, including most recent echocardiogram findings of severity of TR, right ventricular dimensions and output, and other diagnostic results.**
* **Include previous medical therapy, significant comorbidities, such as prior CABG (list year surgery performed, number of vessels grafted), COPD with most recent pulmonary function tests [PFTs], smoking status, chronic kidney disease with most recent BUN/CrCl, etc.**

**Our request**

I urge you to reconsider your denial of the prior authorization, in light of [**patient name**]’s specific clinical need, and the scientific evidence for TriClip System. I believe that in this case TTVr / Tricuspid TEER is medically reasonable and necessary and as such this service should receive prior authorization of coverage and payment.

I have included additional support for your consideration, including medical records, FDA approval letter(s), and an appendix bibliography demonstrating the widespread acceptance of TTVr /Tricuspid TEER.

Please let me know if I can provide any additional information and thank you for your attention.

Sincerely,

[Physician’s name and credentials]

[Title]

[Name of practice]

[Street address]

[City, State, zip code]

[Phone number]

**Enclosures:**

[Prior authorization denial letter]

[Patient relevant medical records/chart notes]

[FDA Approval letter(s) or FDA Instruction For Use]

[Appendix 1. Bibliography- ***Consider using the one provided in the following page***]

**References:**

1. Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting Announcement and Event Material. The U.S. Food and Drug Administration. February 13, 2024. <https://www.fda.gov/advisory-committees/advisory-committee-calendar/february-13-2024-circulatory-system-devices-panel-medical-devices-advisory-committee-meeting>
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4. TriClip™ G4 system. Instructions For Use. The U.S. Food and Drug Administration. (Link not active)

**Appendix 1. Evidence Bibliography**

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8. Freixa X, Arzamendi D, Del Trigo M, et al. The TriClip system for edge-to-edge transcatheter tricuspid valve repair. A Spanish multicenter study. Rev Esp Cardiol (Engl Ed). Oct 2022;75(10):797-804. doi:10.1016/j.rec.2022.01.007
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11. Cepas-Guillen PL, de la Fuente Mancera JC, Guzman Bofarull J, et al. Initial Results after the Implementation of an Edge-To-Edge Transcatheter Tricuspid Valve Repair Program. J Clin Med. Sep 19 2021;10(18)doi:10.3390/jcm10184252
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