**SAMPLE LETTER OF MEDICAL NECESSITY**

**To be considered for prior authorization by physicians for Tricuspid Transcatheter Edge-to-Edge Repair (Tricuspid TEER) procedures**

**Instructions for completing the sample medical necessity letter:**

1. Please **customize** this letter template based on medical appropriateness. The addition of any medical information in the template is at the discretion of the treating physicians and the care team. Text requiring customization is in **RED**.
2. Letters of medical necessity are often key to requesting prior authorization for procedures.
3. For independent consideration and review, please make all changes that you believe appropriate or disregard these suggestions in their entirety.
4. After you have customized the letter,**please delete this page and any specific instructions** for completion, disclaimers, Abbott logos, caution statement, trademarks, and document numbers that are seen throughout the letter, so the health plan does not misinterpret the information.
5. The customer is ultimately responsible for the accuracy and completeness of all claims submitted to third-party payers. Please make sure to check the payer’s reimbursement and eligibility requirements before submitting the request.
6. The FDA-approved label is attached below for more information relevant to any prescribing decisions.

**PLEASE DELETE THIS PAGE BEFORE SUBMITTING THE LETTER TO 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).

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

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

[Physician Letterhead]

Date: [XX/XX/XXXX]

Attention: Prior Authorization and Appeal Department

[Payer contact name]

[Payer contact title]

[Payer]

[Street address]

[City, State, zip code]

[Phone]

[Fax]

**Re: Request for Prior Authorization of Tricuspid Transcatheter Edge-to-Edge Repair (Tricuspid TEER) Using TriClip™ System**

Patient Name: [First and last name]

Policy Holder Name: [First and last name]

Patient date of birth: [XX/XX/XXXX]

SS # [XXX-XX-XXXX]

Insurance ID # [XXXXXXXXXXXXXXX]

Group # [XXXXXXXXXX]

Planned Date of Service: [XX/XX/XXXX]

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

Dear [Payer contact name],

I am writing on behalf of my patient, [patient’s name], requesting prior authorization for Tricuspid Transcatheter Edge-to-Edge Repair (Tricuspid TEER) using the TriClip™ System. The service to be provided is a medically necessary implant at [facility name] on [procedure date].

I have examined this patient and conferred with my colleagues in the multidisciplinary heart team, Dr. [insert first colleague’s name], who specializes in [insert specialty], and Dr. [insert second doctor’s name], who specializes in [insert their specialty]. After a comprehensive case review within the heart team, we have reached a shared decision with [Mr./Miss/MS/Mrs., insert **patient’s** name] that percutaneous repair of the tricuspid valve using the TriClip™ G4 system is medically necessary for this patient’s tricuspid regurgitation (TR).

My patient, [Mr./Miss/MS/Mrs., insert **patient’s** name] also meets the U.S. Food and Drug Administration (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**

Severe TR is a progressive disease associated with debilitating symptoms, physical and social limitations, and poor quality of life. Patients with TR experience fatigue, declining exercise capacity, swelling of the abdomen, legs, or veins of the neck, abnormal heart rhythms, and shortness of breath with activity, which can significantly impact patients’ health status. While these patients have the option to undergo TV surgery, few patients with severe TR undergo surgery due to the high rates of morbidity and perioperative mortality associated with surgery. Medical therapy, which is limited to diuretics, is often ineffective in reducing TR. The high operative risk associated with TV surgery and the lack of effectiveness of medical therapy alone has left patients with severe TR largely untreated.

The TriClip device was designed to offer patients with symptomatic severe TR a safe, minimally invasive option to reduce TR, amelioration of symptoms, and improvement in cardiac function and health status. TriClip was granted Breakthrough Device Designation by the FDA because of the clear unmet need and the lack of satisfactory treatment options.

On February 13th, 2024 (Circulatory System Devices Panel, 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.

**TRILUMINATE Pivotal Randomized Controlled Trial Outcomes**

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 Control 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 **(p<0.001).**
* 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 Device 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.

In summary, TRILUMINATE Pivotal RCT results confirm the effectiveness of TriClip in treating patients with symptomatic, severe TR and improving their health status. TriClip System demonstrated a significant reduction in TR severity, with associated improvement in health status and reduction in heart failure symptoms.

**Patient Clinical History**

[Mr./Miss/MS/Mrs., insert **patient’s** name]’s TR-related clinical findings are attached below for your review.

* Indicate the patient’s **TR severity/grade** [*Table below is the TR severity guide which was utilized in the TRILUMINATE Pivotal RCT*]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Trace/Mild TR | Moderate TR | Severe TR | Massive TR | Torrential TR |
| Vena contracta (biplane, mm) | <3 | 3–6.9 | 7–13 | 14–20 | ≥ 21 |
| PISA radius (mm) | <6 | 6–9 | >9 | >9 | >9 |
| EROA (mm2) | <20 | 20–39 | 40–59 | 60–79 | ≥80 |
| Regurgitant volume (mL) | <15 | 15–44 | 45–59 | 60–74 | ≥75 |
| 3D VCA or quantitative EROA (mm2) |  |  | 75–94 | 95-114 | ≥115 |
| IVC diameter (cm) | <2 | 2.1–2.5 | >2.5 | >2.5 | >2.5 |
| Hepatic flow | Systolic dominant | Systolic blunt | Systolic reversal | Systolic reversal | Systolic reversal |

*PISA: proximal isovelocity surface area; EROA: effective regurgitant orifice area; 3D VCA: three-dimensional vena contracta area; IVC: inferior vena cava.*

* Indicate the patient’s TR-related **signs and symptoms** (shortness of breath, poor quality of life, edema, ascites, exercise intolerance, inability in the activities of daily living, etc)
* Indicate the patient’s existing **risk factors** that could lead to disease progression and/or the TR symptom exacerbation.
* ICD-10-CM **Diagnosis code** and indication for procedure. [Please find the [Abbott Coding Guide](https://www.cardiovascular.abbott/us/en/hcp/reimbursement/sh/coding-coverage.html) here if you need coding guidance]
* Insert all the **current and previous treatments** for the TR disease:
	+ Treatments success or failure (medical therapy ineffective)
	+ Reasons for previous treatment failure
* Attach a copy of TR-related **lab tests and images** (echocardiograms, doppler, etc.)

[Insert why this patient may not be a good candidate for tricuspid repair/replacement surgery, **if applicable and** **decided by the treating physician**:

* Patients might have different reasons for not being eligible for tricuspid surgery; for example, advanced age, high bleeding risk, high operative risk, high rate of post-op mortality, multiple comorbidities, concomitant procedures]

**In closing**

I believe that percutaneous repair of the tricuspid valve using the TriClip System is medically reasonable and necessary and warrants prior authorization of coverage and payment for this service. In my professional opinion, I expect that TriClip Therapy will reduce the patient’s TR severity to moderate or less. I have attached relevant excerpts from the patient’s medical record, including signs and symptoms, treatments tried and failed, and results of diagnostic testing and imaging.

Thank you for the review of this information and your coverage consideration. If you have further questions or concerns, please feel free to contact me.

Sincerely,

[Physician’s name and credentials]

[Title]

[Name of practice]

[Street address]

[City, State, zip code]

[Phone]

**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>
2. Sorajja P, Whisenant B, Hamid N, et al. Transcatheter Repair for Patients with Tricuspid Regurgitation. N Engl J Med. 2023;388(20):1833-1842. doi:10.1056/NEJMoa2300525
3. Spertus JA, Jones PG, Sandhu AT, Arnold SV. Interpreting the Kansas City Cardiomyopathy Questionnaire in Clinical Trials and Clinical Care: JACC State-of-the-Art Review. J Am Coll Cardiol. 2020;76(20):2379-2390
4. TriClip™ G4 system. The U.S. Food and Drug Administration. (Link not active)

**Enclosures:**

Patient medical records/chart notes documenting all the following required clinical information:

* ICD Diagnosis and indication for procedure.
* Relevant history and physical to include member symptoms and pertinent findings.
* Treatments tried, failed, and/or contraindicated, including pharmacologic therapy, if applicable.
* Diagnostic images (e.g., Transesophageal Echocardiography (TEE), intracardiac echocardiography (ICE), or computed tomography [CT]) documenting the suitability for percutaneous repair of the tricuspid valve using the TriClip™ System