**SAMPLE APPEAL TEMPLATE**

**NOT MEDICALLY NECESSARY / INVESTIGATIONAL EXPERIMENTAL**

**Transcatheter Mitral Valve repair (TMVr) or Mitral Transcatheter Edge-to-Edge Repair (M-TEER) for Mitral Regurgitation**

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

1. Please customize the appeal letter template based on the medical appropriateness of TMVr / M-TEER for your patient. Fields required for customization are **highlighted in yellow**.
2. It is important to provide the most complete information to assist with the appeal of a prior authorization denial.
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.

**MitraClip™ G4 System**

**Rx Only**

**Important Safety Information**

**Indications for Use**

* The MitraClipTM G4 System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.
* The MitraClipTM G4 System, when used with maximally tolerated guideline-directed medical therapy (GDMT), is indicated for the treatment of symptomatic, moderate-to-severe or severe secondary (or functional) mitral regurgitation (MR; MR ≥ Grade III  per American Society of Echocardiography criteria) in patients with a left ventricular ejection fraction (LVEF) ≥ 20% and ≤ 50%, and a left ventricular end systolic dimension (LVESD) ≤ 70 mm whose symptoms and MR severity persist despite maximally tolerated GDMT as determined by a multidisciplinary heart team experienced in the evaluation and treatment of heart failure and mitral valve disease.

**Contraindications**

The MitraClip G4 System is contraindicated in patients with the following conditions: Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or post procedural anti-platelet regime; Patients with known hypersensitivity to clip components (nickel / titanium, cobalt, chromium, polyester), or with contrast sensitivity; Active endocarditis of the mitral valve; Rheumatic mitral valve disease; Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

**Potential Complications and Adverse Events**

The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip G4 procedure: Allergic reactions or hypersensitivity to latex, contrast agent, anesthesia, device materials (nickel / titanium, cobalt, chromium, polyester), and drug reactions to anticoagulation, or antiplatelet drugs, Vascular access complications which may require transfusion or vessel repair including: wound dehiscence, catheter site reactions, Bleeding (including ecchymosis, oozing, hematoma, hemorrhage, retroperitoneal hemorrhage), Arteriovenous fistula, pseudoaneurysm, aneurysm, dissection, perforation / rupture, vascular occlusion, Emboli (air thrombotic material, implant, device component); Peripheral Nerve Injury; Lymphatic complications; Pericardial complications which may require additional intervention, including: Pericardial effuse on, Cardiac tamponade, Pericarditis; Cardiac complications which may require additional interventions or emergency cardiac surgery, including: Cardiac perforation, Atrial septal defect; Mitral valve complications, which may complicate or prevent later surgical repair, including: Chordal entanglement / rupture, Single Leaflet Device Attachment (SLDA), Thrombosis, Dislodgement of previously implanted devices, Tissue damage, Mitral valve stenosis, Persistent or residual mitral regurgitation, Endocarditis; Cardiac arrhythmias (including conduction disorders, atrial arrhythmias, ventricular arrhythmias); Cardiac ischemic conditions (including myocardial infarction, myocardial ischemia, and unstable / stable angina); Venous thromboembolism (including deep vein thrombosis, pulmonary embolism, post procedure pulmonary embolism); Stroke / Cerebrovascular accident (CVA) and Transient Ischemic Attack (TIA); System organ failure: Cardio-respiratory arrest, Worsening heart failure, Pulmonary congestion, Respiratory dysfunction / failure / atelectasis, Renal insufficiency or failure, Shock (including cardiogenic and anaphylactic); Blood cell disorders (including coagulopathy, hemolysis, and Heparin Induced Thrombocytopenia (HIT)); Hypotension / hypertension; Infection including: Urinary Tract Infection (UTI), Pneumonia, Septicemia; Nausea / vomiting; Chest pain; Dyspnea; Edema; Fever or hyperthermia; Pain; Death; Fluoroscopy, Transesophageal echocardiogram (TEE) and Transthoracic echocardiogram (TTE) -related complications: Skin injury or tissue changes due to exposure to ionizing radiation, Esophageal irritation; Esophageal perforation, Gastrointestinal bleeding

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[Physician Letterhead]

Month, Day, Year

Attention: Appeals Department

Reference number: XXXXXXXXX

Payer Name

Grievance and Appeals

PO Box XXXXXXX

City, State, Zip Code

FAX: xxx-xxx-xxxx

**Re: Expedited Appeal of Denial for Coverage of** **the Transcatheter Mitral Valve Repair or Transcatheter Edge to Edge Repair for Mitral Regurgitation**

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

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

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

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

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

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

Dear Appeals and Grievances:

I am writing in response to a denial letter recently received, denying approval for transcatheter/ percutaneous mitral valve repair (TMVr) or mitral transcatheter edge to edge repair (M-TEER) to treat symptomatic mitral regurgitation (MR). On behalf of your client and our patient, I respectfully request a re-evaluation of your denial for 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, we have been performing TMVr in our practice for years without any issue. Upon further review of the patient records, I can find no reason for the denial – this patient meets all medical criteria outlined for the procedure.

Mitral Regurgitation (MR) occurs when the mitral valve fails to close completely, causing blood flow to move backward. Mitral regurgitation can be primary (degenerative) or secondary (functional). Transcatheter mitral valve repair offers a safe and effective alternative option for both types of patients; those who are considered to be at prohibitive risk for conventional mitral valve surgery and for those patients who remain symptomatic despite guideline-directed medical therapy. MitraClip™ Therapy addresses a significant unmet clinical need for patients who otherwise are left to face the dismal prognosis of progressive untreated mitral regurgitation.

As a cardiologist experienced in mitral valve disease, I have determined that the patient requires intervention for **[his/her]** significant and symptomatic MR and meets the indicated requirements for TMVr/M-TEER. **[Patient Name]** has been evaluated by a heart team who have determined that **[he/she]** requires transcatheter mitral valve repair for **[his/her]** significant and symptomatic MR.

**[Include the following:**

* **Name and title of cardiac surgeon, how many procedures performed, a report from the surgeon documenting risk factors, STS score and recommendation for MitraClip™ TEER.**
* **List all other physicians who have seen the patient and recommend MitraClip™ TEER and include reports and findings.]**

My patient is an **[age]**-year old **[gender]** who has significant symptomatic MR. **[Include detailed description of patient’s condition (ability to perform daily activities, overall condition, etc.). Provide diagnostic description and ICD-10 diagnosis codes and NYHA class and description].**

**[Describe relevant patient clinical information, including most recent echocardiogram findings of severity of MR, left ventricular dimensions and output, and other diagnostic results. Also include previous pharmacological therapy, significant comorbidities, such as prior CABG (list year surgery performed, number of vessels grafted), COPD with most recent pulmonary function tests [PFTs], chronic kidney disease with most recent BUN/Cr, etc.]**

**Guideline for the Management of Patients with Valvular Heart Disease**

In December of 2020, the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines published updated guidance on mitral valve repair. This joint body, in collaboration with and endorsed by the American Association for Thoracic Surgery, American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons recommend transcatheter mitral valve repair (edge to edge repair) for patients with severe symptomatic primary and or secondary mitral regurgitation[[1]](#footnote-1).

**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 this technology. I believe that in this case TMVr / M-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), National Coverage Determination, society guidance and an appendix bibliography demonstrating the widespread acceptance of TMVr /M-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:**

[Appeal letter]

[Patient medical records/chart notes]

[FDA Approval letters – for both indications]

[Bibliography]

[ACC/AHA 2020 Guideline]

1. 2020 ACC/AHA Guideline for Management of Patients with Valvular Heart Disease: A Report of the American College of Cardiology/ American Heart Association Joint Committee on Clinical Practice Guidelines - <https://doi.org/10.1016/j.jacc.2020.11.018> [↑](#footnote-ref-1)