SAMPLE APPEAL TEMPLATE
NOT MEDICALLY NECESSARY / INVESTIGATIONAL EXPERIMENTAL

MitraClip™ Therapy for TMVr

Instructions for completing the sample appeal letter:

1. Please customize the appeal letter template based on the medical appropriateness of the MitraClip™ Therapy 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.

[Physician Letterhead]

[Date]

Attention: Appeals Department
Reference number: [_____]
[Payer Name]
[Street address]
[City, State, zip code]
[Fax]

Re: Expedited Appeal of Denial for Coverage of the MitraClip™ Therapy for Transcatheter Mitral Valve Repair

Patient Name: _____
Policy Holder Name: _____
Patient ID #: _____
Policy, Group, or Claim # _____
Diagnosis: _____
Date of Procedure: _____

Dear [Payer contact name]:

I am writing in response to a denial letter recently received, denying approval for transcatheter mitral valve repair (TMVr) using the MitraClip™ Delivery System. 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 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 with MitraClip 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 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 treatment with the MitraClip. **[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.**
- **List all other physicians who have seen the patient and recommend MitraClip 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.]

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 with MitraClip 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, and a bibliography demonstrating the use of the MitraClip Delivery System.

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:
[Patient medical records/chart notes]
[FDA Approval letters – for both indications]
[MitraClip Bibliography]

IMPORTANT SAFETY INFORMATION

MITRACLIP™ CLIP DELIVERY SYSTEMS

INDICATIONS FOR USE

The MitraClip™ NTR/XTR Clip Delivery 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 MitraClip™ NTR/XTR Clip Delivery 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™ NTR/XTR Clip Delivery System is contraindicated in patients with the following conditions:

- Patients who cannot tolerate procedural anticoagulation or post procedural antiplatelet regimen
- Active endocarditis of the mitral valve
- Rheumatic mitral valve disease
- Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

WARNINGS

- **DO NOT use MitraClip™ outside of the labeled indication.**
- The MitraClip™ Implant should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.
- Read all instructions carefully. Failure to follow these instructions, warnings and precautions may lead to device damage, user injury or patient injury. Use universal precautions for biohazards and sharps while handling the MitraClip™ System to avoid user injury.
- Use of the MitraClip™ should be restricted to those physicians trained to perform invasive endovascular and transseptal procedures and those trained in the proper use of the system.
- The Clip Delivery System is provided sterile and designed for single use only. Cleaning, re-sterilization and / or reuse may result in infections, malfunction of the device or other serious injury or death.
- Use caution when treating patients with hemodynamic instability requiring inotropic support or mechanical heart assistance due to the increased risk of mortality in this patient population. The safety and effectiveness of MitraClip™ in these patients has not been evaluated.

PRECAUTIONS

- Note the product "Use by" date specified on the package.
- Inspect all product prior to use. Do not use if the package
- Prohibitive Risk Primary (or degenerative)

- Prohibitive risk is determined by the clinical judgment of a heart team, including a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, due to the presence of one or more of the following documented surgical risk factors:
  - 30-day STS predicted operative mortality risk score of
    - ≥ 8% for patients deemed likely to undergo mitral valve replacement or
    - ≥ 6% for patients deemed likely to undergo mitral valve repair
  - Porcelain aorta or extensively calcified ascending aorta.
  - Frailty (assessed by in-person cardiac surgeon consultation)
  - Hostile chest
  - Severe liver disease/cirrhosis (MELD Score >12)
  - Severe pulmonary hypertension (systolic pulmonary artery pressure >2/3 systemic pressure
  - Unusual extenuating circumstance, such as right ventricular dysfunction with severe tricuspid regurgitation, chemotherapy for
  - malignancy, major bleeding diathesis, immobility, AIDS, severe dementia, high risk of aspiration, internal mammary artery (IMA) at high risk of injury, etc.
  - Evaluable data regarding safety or effectiveness is not available for prohibitive risk DMR patients with an LVEF < 20% or an LVESD > 60mm. MitraClip™ should be used only when criteria for clip suitability for DMR have been met.
  - The heart team should include a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease and may also include appropriate physicians to assess the adequacy of heart failure treatment and valvular anatomy.

- Secondary Mitral regurgitation

    - Evaluable data regarding safety or effectiveness is not available for secondary MR patients with an LVEF < 20% or an LVESD > 70 mm.
    - The multidisciplinary heart team should be experienced in the evaluation and treatment of heart failure and mitral valve disease and determine that symptoms and MR severity persist despite maximally tolerated GDMT.

POTENTIAL COMPLICATIONS AND ADVERSE EVENTS

The following ANTICIPATED EVENTS have been identified as possible complications of the MitraClip™ procedure.

Death; Allergic reaction (anesthetic, contrast, Heparin, nickel alloy, latex); Aneurysm or pseudo-aneurysm; Arrhythmias; Atrial fibrillation; Atrial septal defect requiring intervention; Arterio-venous fistula; Bleeding; Cardiac arrest; Cardiac perforation; Cardiac tamponade / Pericardial Effusion; Chordal entanglement / rupture; Coagulopathy; Conversion to standard valve surgery; Deep venous thrombus (DVT); Dislodgement of previously implanted devices; Dizziness; Drug reaction to anti-platelet / anticoagulation agents / contrast media; Dyskinesia; Dyspnea; Edema; Emboli (air, thrombus, MitraClip™ Implant); Emergency cardiac surgery; Endocarditis; Esophageal irritation; Esophageal perforation or stricture; Failure to deliver MitraClip™ to the intended site; Failure to retrieve MitraClip™ System components; Fever or hyperthermia; Gastrointestinal bleeding or infarct; Hematoma; Hemolysis; Hemorrhage requiring transfusion; Hypotension / hypertension; Infection; Injury to mitral valve complicating or preventing later surgical repair; Lymphatic complications; Mesenteric ischemia; MitraClip™ Implant erosion, migration or malposition; MitraClip™ Implant thrombosis; MitraClip™ System component(s) embolization; Mitral stenosis; Mitral valve injury; Multi-system organ failure; Myocardial infarction; Nausea / vomiting; Pain; Peripheral ischemia; Prolonged angina; Prolonged ventilation; Pulmonary congestion; Pulmonary thrombo-embolism; Renal insufficiency or failure; Respiratory failure / atelectasis / pneumonia; Septicemia; Shock, Anaphylactic or Cardiogenic; Single leaflet device attachment (SLDA); Skin injury or tissue changes due to exposure to ionizing radiation; Stroke or transient ischemic attack (TIA); Urinary tract infection; Vascular trauma, dissection or occlusion; Vessel spasm; Vessel perforation or laceration; Worsening heart failure; Worsening mitral regurgitation; Wound dehiscence

CAUTION: This product is 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 eifu.abbottvascular.com or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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