

# Prior Authorization Letter (Letter of Medical Necessity)

Date: \_\_\_\_\_ Patient: \_\_\_\_\_  
Insurance: \_\_\_\_\_ Policy Holder: \_\_\_\_\_  
Insurance Phone #: \_\_\_\_\_ ID #: \_\_\_\_\_  
Insurance Address: \_\_\_\_\_ Group #: \_\_\_\_\_  
\_\_\_\_\_  
SS #: \_\_\_\_\_  
\_\_\_\_\_  
DOB: \_\_\_\_\_

To Whom It May Concern:

The purpose of this letter is to request a predetermination of coverage/prior authorization for the use of Medtronic Melody Transcatheter Pulmonary Valve for the treatment of Right Ventricular Outflow Tract Conduit (RVOT) Dysfunction. RVOT conduit dysfunction can manifest as RVOT conduit obstruction or pulmonary regurgitation, either alone or in combination. Left untreated, RVOT conduit dysfunction can result in decreased effort tolerance.

The intent of the Melody valve implant is to improve the patient's negative symptoms and delay the need for open-heart surgery (many more complications). Melody therapy involves the minimally invasive implantation of a pulmonary valve within the heart. The equipment needed to complete the procedures includes two components: The Melody Transcatheter Pulmonary Valve (TPV) and the Ensemble Transcatheter Valve Delivery System. Using the Ensemble Transcatheter Delivery System, the physician delivers the Melody Valve by catheter through the body's cardiovascular system, and delaying the need to open the chest for open heart surgery. This will minimize patient trauma and offers a quicker patient recovery.

The Melody system received a humanitarian use device designation HUD #07-0180 on July 10, 2007 and received FDA approval under a humanitarian device exemption (HDE) January 25, 2010. Recent studies of the effect of transcatheter pulmonic valve implantation in patients with RVOT dysfunction have shown probable benefit and an acceptable safety profile. Pertinent information about the therapy is attached.

Given this patient's condition, he/she meets clinical indications to use the Melody therapy. I recommend implantation of the Melody therapy as a means to improve this patient's condition. I request confirmation that this therapy is a covered benefit based on medical necessity, and that associated professional fees for the procedure and implant of the Melody Valve will be covered. I also request the charge for the devices, and any other medical supplies associated with the facility costs, be approved.

Thank you for your review of this information and for your coverage consideration. If you have any questions, please contact me at:

Phone #: \_\_\_\_\_

Sincerely,

\_\_\_\_\_, M.D.

Address: \_\_\_\_\_  
\_\_\_\_\_