FDA Premarket Approval

Please note: On January 27, 2015, the Melody TPV System was granted Premarket Approval (PMA) by the Food and Drug Administration (FDA). Melody TPV System was previously approved as a Humanitarian Device Exemption (HDE) by the FDA on January 25, 2010 based on evidence of safety and probable benefit. This PMA approval demonstrates that the Melody TPV System has demonstrated both safety and effectiveness in the management of pediatric and adult patients with Right Ventricular Outflow Tract Conduit (RVOT) dysfunction.

Overview

Medtronic has compiled this information for your convenience. It is always the provider’s responsibility to determine coverage and submit appropriate codes, modifiers, and charges for the services that were rendered. Contact your local carrier/payor for interpretation of appropriate coverage and coding policies. These suggestions will guide you through the prior authorization process for the procedure in which the Melody TPV System is used to deliver the therapy. Many payors require physicians’ offices to submit specific patient information for prior authorization review. The information provided should document the health status of the patient and assure the reviewer that the proposed therapy is the most appropriate treatment alternative for the patient.

Keys to Success in Gaining Prior Authorization

The keys to successful prior authorization and appropriate reimbursement from a patient’s payor include:

▪ Identify a staff member to coordinate all prior authorization and pre-certification processes.
▪ Follow the payor’s conditions for coverage.
▪ Prepare a clear and concise letter of medical necessity.
▪ Educate the payor regarding the therapy, as needed.

Medicare

Medicare does not routinely require prior authorization for services that are considered covered benefits under Medicare. Contact your local carrier for instructions.

Private Payors

Prior authorization is considered essential. Medtronic strongly recommends doing prior authorizations with private payors.

Medical Assistance (Medicaid)

Prior authorization is required. Contact your state authority for instructions.

Indications

The Melody TPV is indicated for use as an adjunct to surgery in the management of pediatric and adult patients with the following clinical conditions:

▪ Existence of a full (circumferential) RVOT conduit that was equal to or greater than 16 mm in diameter when originally implanted AND
▪ Dysfunctional RVOT conduits with a clinical indication for intervention, AND:
  -regurgitation: ≥ moderate regurgitation, AND/OR
  -stenosis: mean RVOT gradient ≥ 35 mm Hg

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.
Steps in the Prior Authorization Process

**Step 1: Collect Information**
- Collect all patient, physician, and payor information
  - Patient’s name
  - Payor
  - Patient’s identification number (often social security number)
  - Implanter’s name
  - Facility where implant will take place
  - Obtain patient consent to release patient information to the payor

Identify diagnosis and corresponding hospital and physician billing codes. Make sure the patient’s diagnosis code/s is for a disease state within the FDA approved indications for Melody Therapy.

**Step 2: Contact the Payor**
- Confirm eligibility and benefits.
- Inquire about coverage for the intended procedure.
- Determine payor requirements for prior authorization. If no prior authorization requirements are necessary, inquire if pre-determination can be filed.

Verbal authorization may be given based on the above information. Written authorization is preferred. Whether authorization is verbal or written, the provider should obtain an authorization number. For written authorization, you will need to provide:
  - The letter of medical necessity/Prior Authorization template letter.
  - Request for Prior Authorization

**Step 3: Send the Requested Information**
Gather all requested materials and mail or fax them to the individual or department responsible for the payor’s prior authorization decisions.

**Step 4: Follow-Up**
Call the insurance payor to verify receipt of the prior authorization request and continue to follow up routinely with the payor until a coverage decision has been made.

**Step 5: Re-verify Eligibility**
When prior authorization has been granted, obtain the prior authorization number for your files and ask if an approval letter will be mailed out. Re-verify the patient’s eligibility to ensure that the patient is still covered by this payor.

**Step 6: Appeal**
If authorization is denied, the physician and patient must decide if the decision will be appealed. For an appeal you will need to:
  - Request information from the payor regarding their appeal process.
  - Send an appeal letter and required materials as directed. Verify receipt of materials.
  - File the appeal within the time limits set by the payor as listed in the denial letter.
  - Patient can also submit a personal appeal to the payor and could contact their employer for assistance.