PRIOR AUTHORIZATION INFORMATION

Harmony™
Transcatheter Pulmonary Valve (TPV)

FDA Premarket Approval
Please note: On March 26, 2021, the Harmony™ transcatheter pulmonary valve (TPV) system was granted premarket approval by the Food and Drug Administration (FDA).

Indication Statement
The Harmony TPV system is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation (i.e., severe pulmonary regurgitation as determined by echocardiography and/or pulmonary regurgitant fraction ≥ 30% as determined by cardiac magnetic resonance imaging) who have a native or surgically repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement.

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 Harmony™ 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 precertification 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
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 Harmony 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 predetermination 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: Reverify 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. Reverify 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.
Indications
The Harmony™ transcatheter pulmonary valve (TPV) system is indicated for use in the management of pediatric and adult patients with severe pulmonary regurgitation (i.e., severe pulmonary regurgitation as determined by echocardiography and/or pulmonary regurgitant fraction ≥ 30% as determined by cardiac magnetic resonance imaging) who have a native or surgically-repaired right ventricular outflow tract and are clinically indicated for surgical pulmonary valve replacement.

Contraindications
The following are contraindications for the use of this device: active bacterial endocarditis or other active infections, known intolerance to Nitinol (titanium or nickel), or an anticoagulation/antiplatelet regimen.

Warnings
General: Implantation of the Harmony TPV system should be performed only by physicians who have received Harmony TPV system training. The transcatheter pulmonary valve (TPV) is to be used only in conjunction with the Harmony delivery catheter system (DCS). This procedure should only be performed where emergency pulmonary valve surgery can be performed promptly. Do not use any of the Harmony TPV system components if any of the following has occurred: it has been dropped, damaged, or mishandled in any way, or if the use-by date has elapsed.

Transcatheter pulmonary valve (TPV): This device was designed for single use only. Do not reuse, reprocess, or reinitialize the TPV. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Do not reinitialize the TPV by any method. Exposure of the device and container to irradiation, steam, ethylene oxide, or other chemical sterilants renders the device unfit for use. The device is packaged with a temperature sensor. Do not freeze the device. Do not expose the device to extreme temperatures. Do not use the device if the arrow on the sensor points to the symbol that indicates that the temperature limit has been exceeded. Do not use the device if any of the following have occurred: the tamper-evident seal is broken, the serial number tag does not match the container label, the arrow on the sensor points to the symbol that indicates that the temperature limit has been exceeded, or the device is not completely covered by the storage solution. Do not contact any of the Harmony TPV system components with cotton or cotton swabs. Do not expose any of the Harmony TPV system components to organic solvents, such as alcohol. Do not introduce air into the catheter. Do not expose the device to solutions other than the storage and rinsing solutions. Do not add or apply antibiotics to the device, the storage solution, or the rinse solution. Do not allow the device to dry. Maintain tissue moisture with irrigation or immersion. Do not attempt to repair a damaged device. Do not handle the valve leaflet tissue or use forceps to manipulate the valve leaflet tissue. Do not attempt to recapture the device once deployment has begun. Do not attempt to retrieve the TPV if any one of the outflow TPV struts is protruding from the capsule. If any one of the outflow TPV struts has deployed from the capsule, the TPV must be released from the catheter before the catheter can be withdrawn. Do not attempt post-implant balloon dilatation (PITD) of the TPV during the procedure, which may cause damage to or failure of the TPV leading to injury to the patient resulting in reintervention.

Delivery catheter system (DCS): This device was designed for single use only. Do not reuse, reprocess, or reinitialize the DCS. Reuse, reprocessing, or re sterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. Do not reuse or reinitialize the DCS. Do not use the device to advance the guidewire, DCS, or any other component without first determining the cause and taking remedial action. Do not remove the guidewire from the DCS at any time during the procedure.

Precautions
General: Clinical long-term durability has not been established for the Harmony TPV. Evaluate the TPV performance as needed during patient follow-up. The safety and effectiveness of Harmony TPV implantation in patients with pre-existing prosthetic heart valve or prosthetic ring in any position has not been demonstrated. The Harmony TPV system has not been studied in female patients of child-bearing potential with positive pregnancy tests.

Before use: Exposure to glutaraldehyde may cause irritation of the skin, eyes, nose, and throat. Avoid prolonged or repeated exposure to the chemical vapor. Use only with adequate ventilation. If skin contact occurs, immediately flush the affected area with water (for a minimum of 15 minutes) and seek medical attention immediately. The TPV and the glutaraldehyde storage solution are sterile. The outside of the TPV container is nonsterile and must not be placed in the sterile field. The TPV and DCS should be used only in a sterile catheterization laboratory (cath lab) environment. Ensure that sterile technique is used at all times. Strictly follow the TPV rinsing procedure. For TPV 25: Ensure that all green contrast media usage. Conduct the procedure under fluoroscopy. Fluoroscopic procedures should make their healthcare providers aware that they have a bioprosthetic valve before being performed promptly. Do not use any of the Harmony TPV system components if any of the following has occurred: it has been dropped, damaged, or mishandled in any way, or if the use-by date has elapsed.

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Potential Adverse Events
Potential risks associated with the implantation of the Harmony TPV may include, but are not limited to, the following: death; valve dysfunction; tissue deterioration; heart failure; cerebrovascular incident; perforation; rupture of the right ventricular outflow tract (RVOT); compression of the aortic root; compression of the coronary arteries; sepsis; pseudoaneurysm; erosion; stent fracture; arrhythmias; device embolization or migration; pulmonary embolism; occlusion of a pulmonary artery; laceration or rupture of blood vessels; device misorientation or misplacement; valve deterioration; regurgitation through an incompetent valve; physical or chemical implant deterioration; paravalvular leak; valve dysfunction leading to hemodynamic compromise; residual or increasing transvalvular gradients; progressive stenosis and obstruction of the implant; hemorrhage; endocarditis; thromboembolism; thrombosis; thrombus; intrinsic and extrinsic calcification; bleeding; bleeding diathesis due to anticoagulant use or factor; pain at the catheterization site; allergic reaction to contrast agents; infection; progressive pulmonary hypertension; progressive neointimal thickening and peeling; leaflet thickening; hemolysis. General surgical risks applicable to transcatheter pulmonary valve implantation: abnormal lab values (including electrolyte imbalance and elevated creatinine); allergic reaction to antiplatelet agents, contrast medium, or anesthesia; exposure to radiation through fluoroscopy and angiography; permanent disability.

Please reference the Harmony TPV system instructions for use for more information regarding indications, warnings, precautions, and potential adverse events.

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