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Department of Health Services Children's Medical Services Network (CMS Net) - Information Bulletin #395

Authorization Instructions for the Melody Valve

Medtronic Melody® Transcatheter Pulmonary Valve (TPV) (Model PB 10) and Medtronic Ensemble® Transcatheter Valve Delivery System (Model NU 10)

Special Instructions:

Special Instructions for the prior authorization review by California Children's Services (CCS) Program office staff and the completion and issuance of a Service Authorization Request (SAR) for the Medtronic Melody® Transcatheter Pulmonary Valve (TPV) (Model PB 10) and Medtronic Ensemble® Transcatheter Valve Delivery System (Model NU 10) -- (Also known as the Melody Valve and the Delivery System) are provided in this document.

CCS County Program Office staff will review prior authorization requests and issue the authorizations for the implantation of and for the Melody Valve and Delivery System.

Background:

The Medtronic Melody® Transcatheter Pulmonary Valve (TPV) (Model PB 10) and Medtronic Ensemble® Transcatheter Valve Delivery System (Model NU 10) has been approved by the Center for Devices and Radiological Health of the Food and Drug Administration (FDA) under Humanitarian Device Exemption (H080002) for the use as an adjunct to surgery in the management of pediatric and adult patients with the following clinical conditions:

1. Existence of a full (circumferential) Right Ventricular Outflow Tract (RVOT) conduit that was equal to or greater than 16 mm in diameter when originally implanted and
2. Dysfunctional RVOT conduits with a clinical indication for intervention, and either:
 - a. Regurgitation: greater than or equal to moderate regurgitation, or
 - b. Stenosis: mean RVOT gradient greater than or equal to 35 mm Hg.

Authorization:

There are two authorizations involved for the Melody Valve and Delivery System. One authorization is issued to the facility Out Patient provider (NPI) number for the Melody Valve and the Delivery System. The second authorization is issued to the cardiologist implanting the valve and the associated codes which are payable by Medi-Cal.

1. Authorization for the Melody Valve and the Delivery System can only be issued to the **Out Patient provider (NPI) number** associated with the facility with a CCS-approved Regional Cardiac Center where the Melody Valve will be implanted.
2. For the cardiologist implanting the valve, the procedure codes associated with the implantation of the Melody Valve can be only be issued to:
 - a. a CCS-approved Pediatric Cardiologist who is a member of a CCS-approved Subspecialty Interventional Cardiac Catheterization (ICC) Program located at a CCS-approved Regional Cardiac Center **and**
 - b. who has been trained by Medtronic, proctored on three cases and who has successfully completed or implanted the Melody Valve on three cases on their own.
 - c. Codes requested by the cardiologist which are payable by Med-Cal and are appropriate for the procedure(s) are to be issued as per usual (i.e. SCG 01, SCG 02, and codes which are not in SCG 01 or 02) by the CCS County Program Office staff.

Note: Individuals who have been certified by Medtronic already meet all the criteria, as certification by Medtronic requires successful implantation of the Melody Valve for ten cases. The following link:

<http://www.medtronic.com/melody/melody-trained-physicians.html>

provides a list of certified Melody Valve Implanters in California. This list includes individuals who may not be a member of a CCS-approved Subspecialty ICC Program. In addition, the list may not be current. CCS county staff who have questions regarding approved providers may contact the State staff listed at the end of this document.

SAR Authorization Instructions for the Melody Valve and Delivery System for CCS only, CCS/Healthy Families, and CCS/ Medi-Cal with unmet share of cost clients:

1. Enter into the Provider Information Section.
 - You must use an **Out Patient provider (NPI) number** on the SAR for the Melody Valve and Delivery System.
2. Enter into the SAR Information Section.
 - Complete the Service Begin Date, Service End Date and Service Request Date.
3. Do not check the EPSDT-SS box.
4. Do not check the State Approved box.
5. Category: Select from the drop downs (scroll to the bottom of the list):
 - Miscellaneous Non-Benefit – Requires County Approval.
6. Service Code Information -- Use Miscellaneous code Z5999 for one unit.

7. Special Instructions area: The following information must be included in addition to any other applicable special language instructions: (See drop down language, Category: Cardiology. Add the name of the cardiologist). **NON-EPSTD-SS SAR approval for Z5999 for the Melody Transcatheter Pulmonary Valve and Delivery System** implanted by Dr. ___add the name___.

For this 'By-Report' Z5999 code, the provider must submit and attach the following items:

- a. Claim (CMS 1500 or current accepted form).
- b. A copy of the CCS authorization.
- c. Invoices related to the Melody Valve and Delivery System (for which there are currently no payable codes).
- d. **Invoice COST** of the devices must be on the invoice.

The claim and invoices for the Melody Valve and Delivery System must be submitted directly to: **Kimie Kagawa, M.D.**

**California Department of Health Care Services
Systems of Care Division; Children's Medical Services
1515 K Street, Suite 400; Sacramento, CA 95814-4040**

Note to the Provider: Do not submit other procedure codes on the claim. They will be deleted.

8. After the CCS County Program office has issued a SAR for the Melody Valve and Delivery System, please email Kimie Kagawa, M.D. at Kimie.Kagawa@dhcs.ca.gov with the SAR number for the purpose of tracking claims and invoices.

SAR Authorization Instructions for the Melody Valve and Delivery System for CCS/Medi-Cal clients (full scope with no share of cost):

1. Enter into the Provider Information Section.
 - You must use an **Out Patient provider (NPI) number** on the SAR for the Melody Valve and Delivery system.
2. Enter into the SAR Information Section.
 - Complete the Service Begin Date, Service End Date and Service Request Date.
3. Check the EPSTD-SS box.
4. Do not check the State Approved box.
5. Category: Select from the drop downs (scroll to the bottom of the list):
 - Miscellaneous Non-Benefit – Requires County Approval.
6. Service Code Information -- Use Miscellaneous code Z5999 for one unit.
7. Special Instructions area: The following information must be included in addition to any other applicable special language instructions: (See drop down language, Category: Cardiology. Add the name of the cardiologist). **EPSTD-SS SAR approval for Z5999 for the Melody Transcatheter Pulmonary Valve and Delivery System** implanted by Dr. ___add the name___.

For this 'By-Report' Z5999 code, the provider must submit and attach the following items:

- a. Claim (CMS 1500 or current accepted form).
- b. A copy of the CCS authorization.
- c. Invoices related to the Melody Valve and Delivery System (for which there are currently no payable codes).
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If you have any questions, please contact State staff:

Kimie Kagawa, M.D. at 916-327-2665; Kimie.Kagawa@dhcs.ca.gov; or
Galynn Thomas, R.N., M.S.N. at 916-322-8785; Galynn.Thomas@dhcs.ca.gov .