

Advancing the Treatment of Heart Failure. Together.

Cordella PA Pressure Sensor

HOP Panel Meeting

August 26-27, 2024



Summary of Request

Endotronix recently received approval for the Cordella Sensor System, which facilitates capturing pulmonary artery pressure (PAP) measurements to help manage heart failure patients and keep them out of the hospital

- The Cordella Sensor System includes an implantable sensor (Cordella Sensor), an external reader used by the patient (Cordella Patient Reader or Cordella Reader) daily to send PAP readings to a secure cloud and a system by which the HCP can help interpret and manage patient care

CMS is proposing to create code GMEM1 to facilitate billing for a replacement external reader

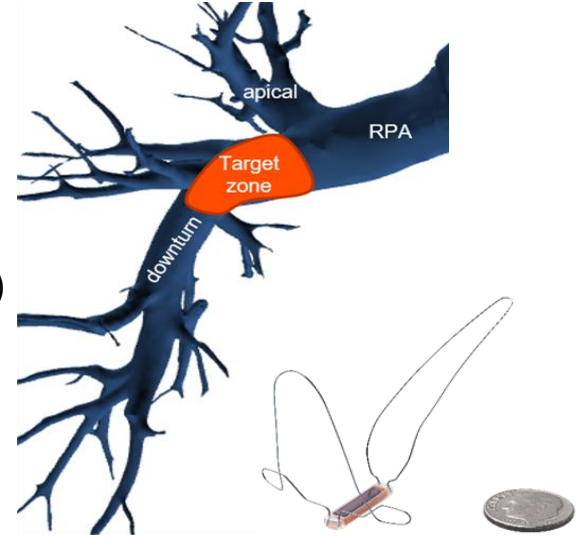
- Endotronix supports this proposal and thanks CMS for proposing this code
- However, we believe the APC assignment of this new code is inappropriate, both clinically and from a resource perspective
 - Proposed APC Assignment: APC 5741, Level 1 Electronic Analysis of Devices with a proposed payment rate of \$37
 - This APC includes procedures for implantable device interrogation that includes capital equipment
 - This new code is for a replacement patient reader that the patient uses daily at home
- We contend a more appropriate APC assignment is New Technology APC 1524 as it more appropriately reflects the acquisition cost of the reader, which is the primary cost associated with this code
 - The payment level of APC 5741 represents ~1% of the cost of the reader
 - We anticipate a low volume of claims as this code will only be used for out of warranty Cordella Reader replacements
 - Until sufficient claims history can be collected, we believe this APC assignment best represents CMS' intention when creating a code to allow for billing of the replacement patient reader

Request that the Advisory Panel recommend assignment of GMEM1 to New Technology APC 1524

Cordella Pulmonary Artery Pressure Sensor System received PMA Approval June 20, 2024

The Cordella PA Pressure Sensor System (Cordella Sensor System) includes:

- Cordella Sensor (permanently implanted in Right Pulmonary Artery)



- Cordella Reader





INDICATIONS FOR USE:

The Cordella Pulmonary Artery Sensor System is intended to measure, record and transmit pulmonary artery pressure (PAP) data from NYHA Class III heart failure patients who are at home on diuretics and guideline-directed medical therapy (GDMT) as well as have been stable for 30 days on GDMT. The device output is meant to aid clinicians in the assessment and management of heart failure, with the goal of reducing heart failure hospitalizations.¹

APC Assignment of GMEM1 for Reader Replacements

- The Cordella Reader is **required** to obtain readings from the Cordella Sensor, without a Cordella Reader, the Cordella Sensor will not function.
 - A Cordella Reader is supplied to the patient at the same time the patient receives the Cordella Sensor, and is covered under warranty for a period of time.
- GMEM1 will be utilized to bill for replacement readers once they are out of warranty
- The current APC assignment of 5741, Level 1 Electronix Analysis of Devices, with a proposed payment of \$36.90 does not adequately cover the cost of the necessary components for proper use of the Cordella Sensor.
 - The current cost for an out-of-warranty replacement Reader is \$3,450
 - The current procedures that map to APC 5741 include QHP interrogation or programming of an implanted device, which is not an adequate description of the activities associated with a Reader replacement.
- Analysis of other clinical APCs found no appropriate APC to which assign GMEM1 based on the cost of the reader

We do not believe the assignment of GMEM1 is appropriate to any clinical APC at this time as there is no existing clinical APC that appropriately captures the hospital resources associated with a replacement Reader.

APC Assignment of GMEM1 for Reader Replacements

- Our analysis suggests the most appropriate APC assignment for GMEM1 is to APC 1524, Level 24 New Technology (\$3,000-\$3,500)
 - Expected hospital costs to acquire a replacement Cordella Reader is \$3,450
 - The primary cost of GMEM1 is the hospital acquisition cost of the Reader
 - We suggest a status indicator of “S” given it should be paid separately if the beneficiary receives other services / procedures during the same outpatient visit
 - We anticipate the volume associated with this code will be relatively low
 - Readers are under warranty for a period of time after the initial implant (and deployment of the Reader to the patient)
 - GMEM1 will only be used for “out-of-warranty” Reader replacements
 - Assignment to APC 1524, New Technology, allows for capture of claims data until there is sufficient claims history to evaluate a potential assignment to a clinical APC.

We fully support CMS’ proposal to create HCPCS code GMEM1 for the replacement of the Reader required for pulmonary artery pressure sensing for heart failure patients.

We urge CMS to assign GMEM1 to APC 1524 for CY2025, allowing for appropriate hospital claims collection to evaluate future clinical APC assignment for this code.

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