New CPT Codes Describe Emerging Technologies in the Treatment of Heart Failure

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For 2017, there are new CPT category III codes describing procedures involving cardiac contractility modulation systems and implantable counterpulsation ventricular assistance devices. These emerging technologies are currently undergoing clinical trials. These codes are scheduled to sunset in January 2022. As noted in the introductory section for the category III codes in CPT, category III codes are archived five years from the date of initial publication or extension unless a modification of the archival date is specifically noted at the time of a revision or change to a code.[1]

Cardiac Contractility Modulation

This year there are new CPT category III codes 0408T-0418T describing procedures involving cardiac contractility modulation systems (CCM), which are designed to treat moderate to severe chronic heart failure. In patients with advanced heart failure, optimal standard medical therapy often fails to provide adequate symptom relief or hemodynamic compensation, and few treatments have been shown to objectively increase exercise functional capacity.[2] CCM signals are non-excitatory signals applied during the absolute refractory period that have been shown to enhance the strength of left ventricular contraction. CCM signals may improve the heart's contractility by modifying the function and expression of certain proteins in the heart muscle, and through that, the function of the heart.[3] Unlike pacing pulses, they do not initiate a new contraction of the heart, but rather increase the heart's force of contraction by improving the function of the cardiac muscle cells.[4] In contrast to a pacemaker or a defibrillator, which modulate the heart's rhythm, the CCM systems' impulses are designed to modulate the strength of contraction of the heart muscle. Unlike pacemakers, these systems stimulate for specific time intervals in order to improve myocardial function. CCM therapy is delivered at regular intervals throughout the day.[5]

A CCM system consists of a pulse generator plus one atrial and two ventricular pacemaker electrodes (leads). The pulse generator is typically implanted in the right pectoral region and is connected to three leads that are threaded through veins into the right side of the heart. Two leads are placed on the right ventricular septum and the other is inserted into the right atrium. One lead is used to sense atrial activity, and the other two are used to sense ventricular activity and deliver CCM signals. The contractility of the heart can be evaluated during the implantation procedure in order to optimize the lead position and the acute response to therapy.

For removal and replacement of the pulse generator and leads, individual codes for removal of the generator (0412T) and removal of the leads (0413T) are used in conjunction with the insertion/replacement system code (0408T). Code 0413T is assigned once for each electrode removed. If only the pulse generator is removed and replaced at the same session without any right atrial and/or right ventricular lead(s) inserted or replaced, 0414T should be reported. If the CCM pulse generator is removed and not replaced, code 0412T should be reported. For removal of the pulse generator and all three leads, code 0412T should be reported for removal of the pulse generator and 0413T should be reported for the lead removal (report once for each electrode removed).

When individual transvenous electrodes are inserted or replaced, 0410T (atrial electrode only) and 0411T (ventricular electrode only) should be reported. The codes for insertion or replacement of the leads should be reported once per lead. When the entire system is inserted or replaced, code 0408T should be reported. Code 0415T should be reported for repositioning of a CCM electrode. The code for repositioning of a previously implanted CCM electrode may not be reported with the codes for insertion or replacement of a total CCM system or insertion or replacement of electrodes only. Revision of the CCM generator skin pocket is included in the codes for insertion or replacement of the entire system, removal of the pulse generator only, and removal and replacement of the pulse generator only (codes 0408T, 0412T, 0414T). Code 0416T should be reported for relocation of the skin pocket for the CCM pulse generator. Relocation of the skin pocket may be necessitated by infection or

erosion. CCM device programming and interrogation (codes 0417T and 0418T) are only reported if performed separately from insertion, replacement, or repositioning procedures.[6]

All catheterization and imaging guidance required to complete a CCM procedure are included in the work of the CCM procedure codes. Left heart catheterization performed at the time of CCM placement, replacement, or revision may not be reported separately.[7]

Aortic Counterpulsation Ventricular Assistance

Also new for 2017 are CPT category III codes for procedures involving implantable aortic counterpulsation ventricular assistance devices (also known as intravascular Ventricular Assist Systems, or iVAS). These devices are designed to provide long-term support for patients with advanced heart failure.[8] Approximately 100,000 individuals per year are diagnosed with advanced heart failure and require some sort of mechanical support.[9]

Counterpulsation decreases left ventricular afterload and energy consumption and improves left ventricular mechanical performance and contractility and active relaxation of the reperfused failing heart.[10] Developers of this device hope that eventually it can be used:

- To stabilize patients until a donor heart becomes available (bridge to transplant)
- To support and rest a heart until it recovers (bridge to recovery)
- For long-term support (destination therapy)[11]

An implantable aortic counterpulsation ventricular assistance device is inserted via the subclavian artery, just below the collar bone, and implanted in the aorta. Insertion of the device does not require major incisions into the chest or open-heart surgery. The system components are not located within the chamber of the heart. The device inflates during diastole to reduce end diastolic ventricular pressure on a long-term basis without re-routing blood flow.[12] The cardiac rhythm is monitored using three implanted subcutaneous electrodes that transmit cardiac electrical information to an implanted skin interface device.

An aortic counterpulsation ventricular assistance device differs from other aortic balloon pumps in that it uses a permanently implanted balloon intended for long-term use, and it involves placement of a vascular graft and a mechano-electrical skin interface containing a programmable processor and implantation of subcutaneous electrodes. An intra-aortic balloon pump (CPT codes 33967, 33968, 33970, 33971, 33973, 33974) is a short-term solution used to stabilize a patient. It is usually removed after 48 hours and serves as a bridge to recovery, transplant, or a left ventricular assist device.[13] Intra-aortic balloon pumps are inserted percutaneously or via an open approach through the femoral artery or ascending aorta. As indicated above, implantable aortic counterpulsation ventricular assistance devices are inserted via the subclavian artery.

Unlike the device described by the new codes, insertion or replacement of extracorporeal and intracorporeal ventricular assist devices (33975, 33976, 33979, 33981, 33982, 33983) requires access to the heart and includes inflow or outflow grafts into the heart, which divert blood flow from the left and/or right chambers of the heart into a pump that pumps blood directly into the corresponding artery (either the aorta and/or pulmonary artery).[14] An implantable aortic counterpulsation ventricular assistance device is not as powerful as these ventricular assist devices, but it can be worn longer than an intra-aortic balloon pump and helps the patient's heart continue to pump until a transplant can be performed.[15] A percutaneous ventricular assist device is a mechanical pump that helps a weakened heart circulate blood to the body. It was developed for short-term use in patients who require acute circulatory support. Percutaneous ventricular assist devices are placed through the femoral artery. The TandemHeart™ and the Impella® device are examples of these devices. CPT codes 33990 and 33991 are reported for percutaneous insertion of ventricular assist devices.

An implantable aortic counterpulsation ventricular assistance device works by sending EKG signals from subcutaneous electrodes to the mechano-electrical interface, which then transmits a signal through an external driveline to an external driver that is carried by the patient. Once the driver receives the EKG signal, a bellows is activated, sending compressed air through the external driveline to the mechano-electrical skin interface in which the compressed air enters the internal driveline and inflates the balloon. After diastole, the bellows creates suction that deflates the balloon.[16]

The CPT codes for aortic counterpulsation ventricular assist devices describe insertion, replacement of the complete system and individual components, relocation of the skin pocket, repositioning of the device or electrodes, programming, and

interrogation.

These codes include all vessel catheterization, diagnostic angiography, radiological supervision and interpretation, and imaging guidance. Insertion or replacement of an implantable aortic counterpulsation assist system (code 0451T) encompasses implantation of all components (counterpulsation device, vascular graft, vascular hemostatic seal, mechano-electrical skin interface, and subcutaneous electrodes), as well as programming of sensing and therapeutic parameters. Removal of a counterpulsation device at the same session as insertion should not be separately reported.

Repositioning of an electrode (code 0460T) should not be reported in conjunction with the codes for insertion or replacement of the implantable aortic counterpulsation ventricular assist system (code 0451T) or subcutaneous electrode (code 0454T). The code for relocation of the skin pocket (code 0459T) includes replacement of the aortic counterpulsation ventricular assist device, mechano-electrical skin interface, and electrodes. The codes for insertion or replacement, removal, or repositioning of electrodes should be reported once for each electrode.[17]

Codes 0462T and 0463T describe device programming and interrogation performed at a different time than an associated surgical procedure (implantation, relocation of skin pocket, repositioning, etc.). These codes may not be reported with each other or with other codes for procedures involving aortic counterpulsation ventricular assistance devices. Both 0462T and 0463T are used to report per-day services.

Notes

[1] American Medical Association. *CPT 2017 Professional*. Chicago, IL: AMA, 2016.

[2] Giallauria, Francesco et al. "Effects of cardiac contractility modulation by non-excitatory electrical stimulation on exercise capacity and quality of life: An individual patient's data meta-analysis of randomized controlled trials." *International Journal of Cardiology* 175, no. 2 (August 1, 2014): 352-357.

[3] Impulse Dynamics. "The Procedure."

[4] Giallauria, Francesco et al. "Effects of cardiac contractility modulation…"

[5] Impulse Dynamics. "The Procedure."

[6] American Medical Association. *CPT 2017 Professional.*

[7] . Ibid.

[8] Easton, John. "New mechanical assist device for advanced heart failure shows promising results during initial evaluation in clinical trial." *ScienceLife*. September 7, 2016.

[9] Ibid.

[10] Kontogiannis, Christos D. "Continuous internal counterpulsation as a bridge to recovery in acute and chronic heart failure." *World Journal of Transplantation* 6, no. 1 (March 24, 2016): 115-124.

[11] Easton, John. "New mechanical assist device for…"

[12] American Medical Association. *CPT 2017 Professional.*

[13] Wong, Grace. "Cardiac Device Wins Fans at U. of C." *Chicago Tribune*, February 5, 2017.

[14] American Medical Association. *CPT 2017 Professional.*

[15] Wong, Grace. "Cardiac Device Wins Fans…"

[16] American Medical Association. *CPT 2017 Professional.*

[17] Ibid.

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