Cohere Medical Policy - Cardiac Contractility Modulation (CCM)

Clinical Guidelines for Medical Necessity Review

Version: 1
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Important Notices

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Guideline Information:

Specialty Area: Diagnostic Imaging
Guideline Name: Cohere Medical Policy - Cardiac Contractility Modulation (CCM)

Literature review current through: 07/03/2024
Document last updated: 07/31/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

Table of Contents

Medical Necessity Criteria

Service: Cardiac Contractility Modulation (CCM)

Recommended Clinical Approach

This service is clinically unproven and not medically necessary. Cardiac contractility modulation (CCM) is a device-based therapy proposed for use in heart failure (HF) patients with decreased ejection fraction who are not candidates for other treatment such as cardiac resynchronization therapy.[1] Electrical impulses delivered to the heart muscle are purported to assist the heart in pumping blood more effectively and potentially reduce symptoms such as breathlessness, fatigue, and lower extremity edema.[2-5]

Medical Necessity Criteria

Indications

- ➔ **Cardiac contractility monitoring** is considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Non-Indications

- ➔ **Cardiac contractility monitoring** is not considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ This procedure is clinically unproven and not medically necessary. There is inconclusive evidence of its effectiveness.

Level of Care Criteria

None

Procedure Codes (CPT/HCPCS)

CPT/HCPCS Code	Code Description
0408T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes
0409T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator only
0410T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; atrial electrode only
0411T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; ventricular electrode only
0412T	Removal of permanent cardiac contractility modulation system; pulse generator only
0413T	Removal of permanent cardiac contractility modulation system; transvenous electrode (atrial or ventricular
0414T	Removal and replacement of permanent cardiac contractility modulation system pulse generator only
0415T	Repositioning of previously implanted cardiac contractility modulation transvenous electrode, (atrial or ventricular lead)
0416T	Relocation of skin pocket for implanted cardiac contractility modulation pulse generator

0417T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable cardiac contractility modulation system
0418T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system

Medical Evidence

Nadeem and colleagues (2020) conducted a systematic review and updated meta-analysis of randomized controlled trials regarding all-cause mortality outcomes of usage of cardiac contractility monitoring (CCM) in patients with dilated cardiomyopathy who were ineligible for cardiac resynchronization therapy (CRT). Patients in this group had dilated cardiomyopathy and were divided into a CCM group and a standard therapy group and were followed for 12 weeks or longer. In their analysis of 930 patients, the CCM therapy group showed no significant reduction in all-cause mortality compared to the standard therapy group. The researchers concluded that there was a need for a large, randomized controlled trial to determine CCM efficacy.[2]

Pipilas et al. (2023) published a systematic review of the literature regarding current and future directions of CCM for heart failure. At the time of their review, only two devices, the Optimizer Smart and the Optimizer Smart Mini had received FDA approval. Their review concluded that in both randomized and nonrandomized clinical trials, New York Heart Association (NYHA) Class II-III patients with left ventricular ejection fraction between 25% and 45% most often benefited from CCM therapy. They stated that a positive effect exists with use of CCM; however, verification and further study in prospective, randomized controlled trials is necessary.[5]

In a 2016 systematic review, Abi-Samra and Gutterman discussed clinical results of the current literature at that time. FDA-approved pharmacological and device-based treatments for heart failure with reduced ejection fraction (HFrEF) were stated to be limited, and CCM could fill the gap in current treatment for selected patients. Regarding long-term outcomes, the writers discuss retrospective trial outcomes, and acknowledge that at that time, there had been no prospective CCM trials with mortality as a primary outcome. The need for such a prospective randomized trial is emphasized. Special applications and evaluations in CCM use include expansion of duration of daily CCM stimulus, use in cardiac resynchronization therapy (CRT) failures, heart failure with preserved ejection fraction, and atrial fibrillation.[4]

According to the 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure, four randomized controlled trials (RCTs) have shown benefits in

exercise capacity and quality of life (QOL), however, as of yet, no benefits in reduction death or hospitalizations.[6-9]

References

1. US Food and Drug Administration (FDA). Summary of safety and effectiveness data (SSED). Optimizer Smart system. Published March 21, 2019. https://www.fda.gov.
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3. Borggrefe M, Mann D. Cardiac contractility modulation in 2018. *Circulation.* 2018;138:2738-2740. doi:10.1161/circulationaha.118.036460.
4. Abi-Samra F, Gutterman D. Cardiac contractility modulation: a novel approach for the treatment of heart failure. *Heart Fail Rev.* 2016; 21:645-660. Doi 10.1007/s10741-016-9571-6.
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9. Abraham WT, Kuck KH, Goldsmith RL, et al. A randomized controlled trial to evaluate the safety and efficacy of cardiac contractility modulation. *J Am Coll Cardiol HF*. 2018;6:874–883.

Clinical Guideline Revision History/Information

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Review History		