Cohere Medicare Advantage Policy - Cardiac Contractility Modulation (CCM)

Clinical Policy for Medical Necessity Review

Version: 2
Cohere Health UMC Approval Date: October 16, 2025
Last Annual Review: October 16, 2025
Revision: Not Applicable
Next Annual Review: October 16, 2026

Important Notices

Notices & Disclaimers:

GUIDELINES ARE SOLELY FOR COHERE'S USE IN PERFORMING MEDICAL NECESSITY REVIEWS AND ARE NOT INTENDED TO INFORM OR ALTER CLINICAL DECISION-MAKING OF END USERS.

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Other Notices:

Policy Information:

Specialty Area: Diagnostic Imaging
Policy Name: Cohere Medicare Advantage Policy - Cardiac Contractility Modulation (CCM)
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

Table of Contents

Medical Necessity Criteria

Service: Cardiac Contractility Modulation (CCM)

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.[1]

- National Coverage Analysis (NCA). Cardiac contractility modulation (CCM) for heart failure (CAG-00469N)

Description

Cardiac contractility modulation (CCM) is a device-based therapy proposed for heart failure (HF) patients with decreased left ventricular ejection fraction (LVEF) who are not candidates for other treatments, such as cardiac resynchronization therapy.[2] 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.[3,4] A series of 1-3 pulses (4.5–7.5 V) is generated for approximately 5 milliseconds during the absolute refractory period of a cardiac cycle. Stimulation cycles are typically 1 hour in duration, with 7 cycles throughout the day and breaks of 2-3 hours per day.[5,6]

Medical Necessity Criteria

Indications

Cardiac contractility monitoring (CCM) is considered appropriate if **ALL** of the following are **TRUE**:

- The patient is enrolled in an approved clinical trial by the Centers for Medicare & Medicaid Services (CMS), including **ANY** of the following[1,2,7-9]:
  - Post Approval Study (PAS) of the OPTIMIZER Smart and CCM Therapy (PAS) (NCT03970343); **OR**
  - Assessment of CCM in HF With Higher Ejection Fraction (AIM HIGHer) (NCT05064709); **OR**
  - Assessment of Combined CCM and ICD Device in HFrEF (INTEGRA-D) (NCT05855135) (Note: This trial is active but no longer recruiting as of 07/31/25); **AND**
- **ANY** of the following:
  - The patient has signed a consent form for a CMS-approved NCT trial; **OR**
  - The patient meets the Inclusion Criteria and none of the Exclusion Criteria (see NCT links above), and the Provider participates at a Designated site.

Non-Indications

Cardiac contractility monitoring (CCM) is not considered appropriate if **ANY** of the following is **TRUE**:

- The patient has a mechanical cardiac assist device; **OR**
- Heart transplant recipient[1]; **OR**
- The patient is less than or equal to 17 years of age[1]; **OR**
- For heart failure (HF) management outside of a CMS-approved study; **OR**
- Mechanical tricuspid valve is present.[2]

Level of Care Criteria

Inpatient or Outpatient

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
C1824	Generator, cardiac contractility modulation (implantable)
K1030	External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Evaluation of Clinical Harms and Benefits

Clinical determinations for Medicare Advantage beneficiaries are made in accordance with 42 CFR 422.101 guidance outlining CMS's required approach to decision hierarchy in the setting of NCDs/LCDs identified as being "not fully established". When clinical coverage criteria are "not fully established" Medicare Advantage organizations are instructed to create publicly accessible clinical coverage criteria based on widely-accepted clinical guidelines and/or scientific studies backed by a robust clinical evidence base. Clinical coverage criteria provided by Cohere Health in this manner include coverage rationale and risk/benefit analysis.

Clinical coverage criteria for cardiac contractility modulation (CCM) were fully defined and established by NCDs and/or LCDs. Cohere Health did not supplement this policy with any additional criteria or interpretations.

Medical Evidence

Yuecel et al. (2024) compared cardiac contractility monitoring (CCM) and cardiac resynchronization therapy for patients with chronic heart failure (HF). Outcomes at 12-month follow-up were similar; however, hospitalizations occurred more frequently for CCM patients than for those who received cardiac resynchronization therapy (CRT). The authors noted that including the timing of the procedures and the correlation with the progression and stage of HF was a limitation.[10]

Pipilas et al. (2023) published a systematic literature review regarding the current and future directions of CCM for HF. At the time of the review, only two devices, the Optimizer Smart and the Optimizer Smart Mini, had received FDA approval. The review concluded that in both randomized and nonrandomized clinical trials, New York Heart Association (NYHA) Class II-III patients with left ventricular ejection fraction (LVEF) between 25% and 45% most often benefited from CCM therapy. A positive effect exists with CCM; however, verification and further study in prospective, randomized controlled trials are necessary.[11,12]

Nadeem et al. (2020) conducted a systematic review and updated meta-analysis of randomized controlled trials regarding all-cause mortality outcomes of the usage of CCM in patients with dilated cardiomyopathy who were ineligible for 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. Analysis of 930 patients found that 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.[13]

Three randomized controlled trials (RCTs) were conducted on the safety and efficacy of CCM. Abraham et al. (2018) found that CCM was effective for patients with moderate to severe HF; however, the study was small (160 patients) and the limited follow-up did not allow for evaluation of long-term effects (e.g., hospitalization, mortality).[14] Kadish et al. (2011) performed an RCT with 428 patients with advanced HF. While therapy was found to be safe and

effective, there was no improvement in the ventilatory anaerobic threshold (VAT).[15] Borggrefe et al. (2008) conducted a randomized, double blind, crossover study of 164 symptomatic patients with HF. Outcomes were positive; however, the authors noted that the short duration of 3 months was a limitation of the study, as CCM therapy could require a longer period of time.[16]

Müller et al. (2017) also conducted a two-year multicenter study of CCM in patients with heart failure concluded that CCM provides a safe and effective long-term symptomatic and functional improvement in heart failure, independent of baseline LVEF, and was associated with a safety profile similar to published device trials.[17]

In a systematic review, Abi-Samra and Gutterman (2016) discussed the 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 discussed retrospective trial outcomes and acknowledged 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 was emphasized. Special applications and evaluations in CCM use include expansion of the duration of daily CCM stimulus, use in CRT failures, heart failure with preserved ejection fraction, and atrial fibrillation.[18]

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 reducing death or hospitalizations have been shown.[19]

References

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Policy Revision History/Information

Original Date: October 24, 2024		
Review History		
Version 2	10/16/2025	Annual review. Policy was previously non-covered. Added indications for coverage and expanded non-indications. Added HCPCS C1824 and K1030. Simplified Harms and Benefits section. Expanded the Medical Evidence section; added 5 citations.