Cohere Medicare Advantage Policy - Cardiac Contractility Modulation (CCM)

Clinical Guidelines for Medical Necessity Review

Version: 1
Effective Date: October 24, 2024

Important Notices

Notices & Disclaimers:

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Other Notices:

Guideline Information:

Specialty Area: Cardiovascular Disease
Guideline Name: Cohere Medicare Advantage Policy **-** Cardiac Contractility Modulation (CCM)

Date of last literature review: 10/22/2024
Document last updated: 10/23/2024
Type: [**X**] Adult (18+ yo) | [**X**] Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Cardiac Contractility Modulation (CCM)

Benefit Category

Not Applicable

Related CMS Documents

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

- There are no NCDs and/or LCDs for 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 heart failure (HF) patients with decreased left ventricular ejection fraction (LVEF) who are not candidates for other treatments 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]

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of cardiac contractility modulation (CCM). This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Meta-analysis of randomized controlled trials (RCTs) of all-cause mortality outcomes of usage of cardiac contractility monitoring (CCM)

in patients with dilated cardiomyopathy and ineligible for cardiac resynchronization therapy (CRT) revealed no significant reduction in all-cause mortality compared to standard therapy.[2]
- CCM has not shown any impact on hospitalization or death in patients with cardiomyopathy in randomized controlled trials (RCTs).[6-9]
- Hospitalizations have occurred more frequently for patients with CCM those with cardiac resynchronization therapy and defibrillator (CRT-D).[10]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- A retrospective study comparing patients with cardiac contractility modulation (CCM) versus those with cardiac resynchronization therapy with defibrillator (CRT-D) showed that intrinsic QRS width was stable with CCM.[10]
- A study comparing the Optimizer Smart and the Optimizer Smart Mini CCM devices 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.[5]
- Four randomized controlled trials (RCTs) have shown benefits in exercise capacity and quality of life (QOL) with CCM therapy.[6-9]
- A 2-year multi-site evaluation of CCM in patients with heart failure concluded that CCM provides 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.[11]
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ **Cardiac contractility monitoring (CCM)** 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 (CCM)** is not considered appropriate if **ANY** of the following is **TRUE**:
  - ◆ This is not applicable, as there are no indications.

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

Disclaimer: G, S, I, and N Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

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 literature review regarding the 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 CCM; however, verification and further study in prospective, randomized controlled trials is necessary.[5]

In a 2016 systematic review, Abi-Samra and Gutterman 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 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 reducing death or hospitalizations.[6-9]

References

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Clinical Guideline Revision History/Information

Original Date: October 24, 2024		
Review History		