Policy Number	**MED202.068**
Policy Effective Date	**12/15/2025**

Cardiac Contractility Modulation (CCM) Device

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Insertion, removal or replacement of a cardiac contractility modulation (CCM) device **is considered experimental, investigational and/or unproven** for all indications, including but not limited to heart failure.

Policy Guidelines

None.

Description

Heart failure (HF) is a chronic progressive condition which occurs when the heart is unable to pump sufficient blood to the body's needs for blood and oxygen. (1) Many conditions can contribute to HF including but not limited to a history of a prior myocardial infarction (heart attack), coronary artery disease (CAD), abnormal heart valves, diabetes, severe lung disease, heart muscle disease (i.e., dilated cardiomyopathy, hypertrophic cardiomyopathy, myocarditis), abnormal heart rhythm (arrhythmia or dysrhythmia), sleep apnea, severe anemia, obesity,

hyperthyroidism, congenital heart disease, or uncontrolled hypertension. (2) Physicians usually classify patients' HF according to the severity of their symptoms. (3)

Symptoms

Patients with HF may exhibit symptoms immediately or the symptoms may progress slowly thus, going unnoticed until symptoms progressively worsen. Symptoms of HF may include shortness of breath, persistent coughing or wheezing, edema, unusual fatigue, lack of appetite or nausea, impaired thinking and elevated heart rate. (3)

Diagnostic Evaluation

Providers may perform a series of diagnostic tests which may include blood tests, electrocardiogram, chest x-ray, stress test and echocardiogram (ECG) to aide in diagnosing HF. The ECG is used primarily to evaluate heart structure, function and cardiac status based on the ejection fraction (EF) which monitors overall heart strength. A normal EF is greater than 50%, but in HF, the EF can fall to values less than 40% resulting in noticeable symptoms even at rest. In some cases, HF can occur even with a normal EF when the heart muscle becomes stiff from conditions such as hypertension. (4)

The two most common classification systems for diagnosing HF are the New York Heart Association (NYHA) Functional Classification tool (Table 1) which uses a symptom and objective-based scale with four categories ranging from Class I to Class IV, and the American College of Cardiology/American Heart Association (ACC/AHA) scale (Table 2) which uses a stage-based classification system using the letters from A through D. The ACC/AHA system does not replace, but complements, the NYHA classification system. Physicians will often use them concurrently to develop an individual plan of care. (4)

The NYHA Functional Classification tool (Table 1) evaluates the patient's physical activity limitations based on their individual HF symptoms and is divided into functional classifications of symptoms and objective assessment of symptoms.

Table 1. NYHA Functional Classification Tool (4)

Patients Symptoms	**Objective Assessment**
Class I. No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).	Class A. No objective evidence of cardiovascular disease. No symptoms and no limitation in ordinary physical activity.
Class II. Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea.	Class B. Objective evidence of minimal cardiovascular disease. Mild symptoms and slight limitation during ordinary activity. Comfortable at rest.

Class III. Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.	Class C. Objective evidence of moderately severe cardiovascular disease. Marked limitation in activity due to symptoms, even during less-than-ordinary activity. Comfortable only at rest.
Class IV. Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort is increased.	Class D. Objective evidence of severe cardiovascular disease. Severe limitations. Experiences symptoms even while at rest.

Table Key: NYHA: New York Heart Association.

Table 2. ACC/AHA Stages of Heart Failure (5)

A	At high risk for heart failure but without structural heart disease or symptoms of heart failure.
B	Structural heart disease but without signs or symptoms of heart failure.
C	Structural heart disease with prior or current symptoms of heart failure.
D	Refractory heart failure requiring specialized interventions.

Table Key: ACC/AHA: American College of Cardiology/American Heart Association.

Treatment of Heart Failure

Receiving proper treatment for HF is important to stop or delay the progression of HF. The goal of treatment is to correct underlying pathology, improve and manage symptoms, prevent worsening of the condition including organ damage, reduce the frequency of hospitalizations, and to prolong the patient's life. (6) Patients typically receive medications including but not limited to angiotensin receptor neprilysin inhibitors (ARNI), angiotensin-converting enzyme (ACE), angiotensin II receptor blockers inhibitors, beta blockers, diuretics, aldosterone antagonists, inotropes, and digoxin to aide in managing the patient's symptoms. (7) In addition to medications, HF patients may require surgery (i.e., coronary bypass surgery, heart valve repair or replacement, heart transplant) and/or implantable devices (i.e., implantable pacemaker, implantable cardioverter-defibrillator (ICD), cardiac resynchronization therapy (CRT) and/or biventricular pacing, and ventricular assist devices (VADs). (8)

Cardiac contractility modulation (CCM) is a device-based therapy for treating patients with chronic moderate to severe HF (NYHA class III), who are not suited for treatment with other HF devices such as CRT to restore a normal timing pattern of the heartbeat. CCM is a non-excitatory electrical device-based approach proposed to enhance ventricular contractile strength of the failing myocardium, independently of synchrony of myocardial contraction. The CCM implantable device applies relatively high-voltage (≈7.5 V), long-duration (≈20 milliseconds), biphasic electric signals to the right ventricular septal wall during the absolute myocardial refractory period. Accordingly, CCM signals do not elicit a new contraction but potentially modifies the entry of calcium into the cardiomyocyte to enhance cardiac contractility. (9, 10)

Regulatory Status

In March 19, 2019, the Optimizer® Smart System (P180036) received United States (US) Food and Drug Administration (FDA) premarket approval. The device, which delivers CCM™ therapy, is indicated to improve 6-minute hall walk distance, quality of life (QOL), and functional status of NYHA Class III HF patients who remain symptomatic despite guideline directed medical therapy, who are in normal sinus rhythm, are not indicated for CRT, and have a left ventricular EF ranging from 25% to 45%. The Optimizer® Smart System includes an implantable device with leads (similar in size to a pacemaker) and an external charging station.
Product Code: QFV (9, 11)

Furthermore, in October 2021, the FDA approved a modification of labeling for the Optimizer Smart System (P180036/S008), allowing the removal of "normal sinus rhythm" (NSR) from the indications for use statement. (12)

Rationale

This policy is based on a review of relevant professional association recommendations.

National Institute of Health Care and Excellence (NICE)
The 2019 NICE guidance for cardiac contractility modulation (CCM) device implantation for heart failure (HF) includes the following recommendations:

- The evidence on CCM device implantation for HF raises no major safety concerns. However, the evidence on efficacy is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. (13, 14)
- Further research should ideally be in the form of randomized controlled trials (RCTs). These should report details of patient selection, duration and timing of stimulation, and duration of effect of stimulation. Outcomes should include ejection fraction (EF), oxygen consumption, New York Heart Association (NYHA) classification and patient-reported outcomes, including quality of life (QOL). (14)

<u>European Society of Cardiology</u>
The 2021 European Society of Cardiology guideline for the diagnosis and treatment of HF (15) notes that CCM was associated with a small improvement in exercise tolerance and QOL in patients with NYHA class III-IV HF, with an left ventricular ejection fraction (LVEF) ≥ 25% to ≤ 45% and QRS duration < 130ms. However, the evidence was considered insufficient to support specific guideline recommendations for a reduction in mortality or hospitalization. The guidelines recommended larger RCTs for CCM therapy.

<u>American Heart Association (AHA)/ American College of Cardiology (ACC)/Heart Failure Society of America (HFSA) et al.</u>
The 2022 AHA/ACC/HFSA guideline for the management of HF (16) states under section 7.4.2 (other implantable electrical interventions) that "CCM is a device-based therapy that involves applying relatively high voltage, long duration electric signals to the RV [right ventricular] septal wall during the absolute myocardial refractory period, has been associated with augmentation

of LV contractile performance. CCM is FDA-approved for patients with NYHA class III with LVEF of 25% to 45% who are not candidates for CRT. Four RCTs have shown benefits in exercise capacity and QOL but, as of yet, no benefits in death or hospitalizations. Most patients in these trials were class III CHF [congestive heart failure]".

In a 2025 joint publication on appropriate use criteria for implantable cardioverter-defibrillators, cardiac resynchronization therapy (CRT), and pacing from the ACC/AHA/HFSA et al. (17), the following statement was offered on CCM: "The full effect of CCM on HF morbidity and mortality requires further investigation."

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0408T, 0409T, 0410T, 0411T, 0412T, 0413T, 0414T, 0415T, 0416T, 0417T, 0418T
HCPCS Codes	C1824, K1030

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
12/15/2025	Document updated. Coverage unchanged. Added references 5, 11 and 17; others updated and some removed.
05/15/2024	Reviewed. No changes.
05/01/2023	Document updated with literature review. Coverage unchanged. Added references 1, 7, 12, 13, 29-31 and 36; others updated/removed.
12/01/2022	Reviewed. No changes.
08/01/2021	Document updated with literature review. Coverage unchanged. Added references 1, 3, 4, 6-8, 21-25, 29; others updated/removed.
04/01/2020	Document updated with literature review. Coverage unchanged. Added references 2-4, 9, 11-15, 17-19. Some references removed.
10/01/2018	Reviewed. No changes.
10/15/2017	Document updated with literature review. Coverage unchanged.
10/01/2016	Reviewed. No changes.
01/01/2016	New medical document. Insertion, removal or replacement of a cardiac contractility modulation (CCM) device is considered experimental, investigational and/or unproven for all indications, including but not limited to heart failure.