
Medical Policy



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***Current Policy Effective Date: 5/1/26**
(See policy history boxes for previous effective dates)

Title: Cardiac Contractility Modulation (i.e., Optimizer Smart) for the Treatment of Heart Failure

Description

Cardiac contractility modulation (CCM) therapy was designed to increase the strength of the hearts contractions in order to supply adequate blood flow to the body and prevent a backup of blood in the veins which cause congestion in the lungs, extremities, and other organs.

Medical Policy Statement

The use of cardiac contractility modulation therapy (i.e., Optimizer Smart System) is experimental/investigational. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0408T	0409T	0410T	0411T	0412T	0413T
0414T	0415T	0416T	0417T	0418T	C1824
K1030					

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Background

The Optimizer® Smart System (Mini and Lite; Impulse Dynamics) is a minimally invasive implantable stimulation device that was intended to treat adults with moderate-to-severe chronic heart failure who are symptomatic despite receiving optimal medical therapy. The device is implanted under the skin in the upper chest wall, generally in the right pectoral region. It is then connected to leads which are placed in the heart's right ventricular septum. Once programed, the Optimizer delivers non-excitatory electrical pulses to the heart muscle during the absolute refractory period (specific time of the beating cycle) for 5 to 7 hours a day, in 1 hour treatments that are separated by regular intervals. The device is charged by the user 1 time a week for an hour, using an external charger. In contrast to a pacemaker, CCM therapy is designed to modulate the strength of contraction of the heart muscle rather than the rhythm.

The electrical impulses trigger physiological processes in the heart's muscular cells, which are purported to create an impact on the cellular function at the molecular level thereby improving heart function. The therapy is intended to enhance the individuals physical ability and wellbeing.

Congestive Heart Failure

Congestive heart failure (CHF) is a serious medical condition and occurs when the heart muscle is unable to pump sufficient blood to the body to support the organs. The most frequently used measure of heart function is the left ventricular ejection fraction (LVEF). Normal LVEF ranges from 50–75% at rest. Severe heart failure can reduce LVEF to < 35%. According to the Centers for Disease Control nearly 6.7 million adults ≥ 20 years old are currently diagnosed with HF. Currently there is no cure for HF, but early diagnosis and treatment can improve quality and quantity of life. Therapy consists of a combination of medications, reducing sodium, drinking less liquid, physical activity, and heart transplants.

The FDA granted premarket approval (2019) for the Optimizer Smart System to be used for treating individuals with chronic, moderate-to-severe heart failure who are not suited for treatment with other heart failure devices such as cardiac resynchronization therapy to restore a normal timing pattern of the heartbeat.

Summary of Evidence

The FDA premarket approval (2019) of the OPTIMIZER Smart System is based on preliminary findings reported of 389 participants with moderate-to-severe HF (Kadish et al [2011]: FIX-HF-5 subgroup, n=229; Abraham et al [2015; 2018]: FIX-HF-5C, n=160) from 2 randomized, multi-

center clinical trials that have not been published in a peer-reviewed journal. Restrictions were placed on the PMA that require an ongoing study to confirm long-term safety and efficacy of the device. In 2024, the FDA issued a class 2 device recall for Optimizer Smart Mini and Optimizer Lite based on a software design that has caused a malfunction in certain models.

Ongoing trials are attempting to identify the ideal target population. To date, data does not indicate reductions in hospitalizations for heart failure or mortality. Peer reviewed articles agree with the promise the technology holds but have determined that larger, well-conducted, double blind RCTs are necessary to fill knowledge gaps regarding target populations and associated efficacy. Peer reviewed publications have limitations which include: lack of a control group, data indicating improvement in NYHA, Minnesota Living with Heart Failure Questionnaire (MLWHFQ), a lack of evidence regarding if the use of pharmacological treatment for heart failure could have increased LVEF in these patients, and registry follow-up testing was performed based on clinical need, which may have limited the number of individuals available with outcome data related to LVEF and exercise tolerance including 6-min walk test, and peak VO₂. The current evidence base is insufficient to support the use of CCM therapy with the OPTIMIZER Smart System in individuals with chronic, moderate-to-severe heart failure.

Rationale

The original technology for CCM was developed by Impulse Dynamics. Per the Summary of Safety and Effectiveness Data (SSED; 2019) posted on the FDA site, the FDA evaluated the original device in a trial (FIX-HF-5 Phase II) that did not demonstrate efficacy. The original FIX-HF-5 study used a broader group of HF participants and end points that were difficult to achieve in the clinical trial. Ultimately, the trial failed, but subgroup analysis of the FIX-HF-5 study showed which participants could possibly benefit from use of the device.

Kadish et al (2011) conducted a randomized controlled prospective study (FIX-HF-5) to evaluate the safety and efficacy of CCM in advanced HF. A total of 428 adults with NYHA class III or IV, narrow QRS (defined as less than 130 msec duration) and EF less than or equal to 35% were randomly assigned to receive optimal medical therapy (OMT) plus CCM (n = 215), or OMT alone (n = 213). The primary efficacy endpoint, required by the U.S. FDA, was the change from baseline in the ventilatory anaerobic threshold (VAT) measured on a cardiopulmonary exercise test. Secondary efficacy endpoints were peak VO₂ (pVO₂), and quality of life (QOL) assessed by the Minnesota Living with Heart Failure Questionnaire (MLWHFQ) at 6 months. The primary safety endpoint was a test of non-inferiority between groups at 12 months for the composite of all-cause mortality and hospitalizations through 50 weeks. While VAT did not improve at 6 months, CCM significantly improved pVO₂ (p = 0.024) and MLWHFQ (p <0.0001), respectively, over OMT; 48 % of OMT and 52 % of CCM patients experienced a safety endpoint, which satisfied the non-inferiority criterion (p = 0.03). Post-hoc, hypothesis-generating analysis identified a subgroup (characterized by baseline greater than or equal to 25 and NYHA class III symptoms) in which all parameters were improved by CCM. The authors concluded that further study is required to clarify the role of CCM therapy in refractory HF.

Since the original FIX-HF-5 study met its primary safety end point but did not reach its primary efficacy end point Abraham et al (2015) designed a confirmatory study (FIX-HF-5C) to prospectively confirm the efficacy of CCM in the FIX-HF-5 study population. The engineers

determined that the FIX-HF-5C study would enroll 230 subjects with NYHA functional class III or ambulatory class IV symptoms despite OMT, having a QRS duration < 130 ms, and a left ventricular EF 25%-45%. It was determined that the primary efficacy assessment would be based on changes in peak VO₂ between groups at 6 months of follow-up. Bayesian statistics were to be used to combine the prospectively collected FIX-HF-5C data with those of the original FIX-HF-5 study. The study was anticipated to require 1 year for recruitment and an additional 6 months until the last enrolled patient has reached the study end point.

Abraham et al (2018) reported results from the FIX-HF-5C confirmatory study (NCT01381172). A total of 160 participants were randomized to continue OMT (n=86) or CCM (treatment, n=74, unblinded) for 24 weeks. The primary efficacy endpoint was met with a peak VO₂ between groups of 0.84 (95% Bayesian credible interval: 0.123 to 1.552) ml O₂/kg/min. The following secondary outcomes, Minnesota Living With Heart Failure questionnaire (p<0.001), NYHA functional class (p<0.001), and 6-min hall walk (p=0.02), were all significantly better in the treatment group compared to the control group. Sixty-eight of the 74 subjects assigned to the CCM treatment group underwent device implantation with 7 device-related events reported (89.7% complication-free rate). There was a reduction in the composite of cardiovascular death and HF hospitalizations from 10.8% to 2.9% (p=0.048). There was 1 death related to sepsis at 164 days after device implantation in the treatment group following surgery for an incarcerated hernia. Long-term risks of infection are not known at this time. Authors concluded that additional studies are needed to confirm the impact of CCM on mortality in the current target population and beyond the 24-week follow-up in this study. Recommendations for future studies included exploring the benefit of CCM in individuals with prolonged QRS duration in addition to CRT, in particular CRT non-responders.

In 2019 the Optimizer Smart System received FDA PMA approval as a restricted device based on outcomes from both the FIX-HF-5 and the FIX-HF-5C trials. As a requirement of the PMA, the FDA required a post-approval study to provide long-term safety and effectiveness data for the device. The study was required to be a prospective, multi-center, non-randomized, single arm open label study with approximately 620 enrolled subjects, such that 500 implanted subjects reach the 36-month follow-up. The study was assigned the following required safety endpoints:

- The composite of device- or procedure-related complication free rate at 12 months post-index implantation procedure exceeds 75%. Procedure-related complications through the end of 30 days following the index procedure and OPTIMIZER device-related complications occurring through the end of 1 year following the index procedure shall contribute to the composite complication rate.
- Comparison of the observed mortality rate to the predicted mortality for the patient group according to the Seattle Heart Failure Model (SHFM) as per protocol follow-up schedule.
- An assessment of the OPTIMIZER device-related complications and observations occurring during the 3-year period following the index procedure.

The study's effectiveness endpoints were assigned as follows:

Monitor changes in Quality of Life (QoL), as measured by the Minnesota Living with Heart Failure Questionnaire (MLWHFQ), from baseline to per protocol defined time intervals following index procedure.

- Clinical assessment of New York Heart Association (NYHA) functional class. A 1-class change in functional class at per protocol defined time intervals shall be considered clinically significant.

- Clinical assessment of changes in left ventricular ejection fraction (LVEF) and end-systolic volume (ESV) from baseline at per protocol defined time intervals.
- Clinical assessment of changes in NT-proBNP from baseline at per protocol defined time intervals.
- Clinical assessment of changes in QRS duration from baseline at per protocol defined time intervals.

Based on information received from the clinical trial website, the study is ongoing (NCT03970343; see Supplemental information below).

In 2024, the FDA issue a class 2 device recall for the Optimizer model CCM X11 implantable Smart Mini and Lite devices. It was determined that OPTIMIZER devices may cease to deliver CCM therapy if the device incorrectly detects a charging error. Software design is believed to have caused the malfunction and the firm is currently working on a software update to address the issue.

CCM is currently available in Europe and ongoing studies are attempting to identify the ideal target population and accumulate additional outcome data. Although long-term application of CCM seems to improve exercise tolerance and quality of life in individuals with moderate to severe heart failure, to date, no data have demonstrated reductions in hospitalizations for heart failure or mortality (Lyon et al [2013]).

Initially, designed for treating patients with sinus rhythm and narrow QRS, Impulse Dynamics expanded its CCM applications to include those suffering from atrial fibrillation and individuals with wide QRS who do not respond to cardiac resynchronization therapy (CRT). Individuals can be considered for CCM therapy if they meet the following criteria: (a) ejection fraction (EF) between 25% and 45%; (b) QRS duration less than 130 ms; (c) New York Heart Association (NYHA) class 3 or 4; and (d) history of HF treated with stable medications for at least 90 days. Only 5.1% of individuals suffering from heart failure might benefit from CCM. Although this is a very small proportion of the heart failure population, Dulai et al (2021) pointed out that this population does not have any other device option for their condition.

Giallauria et al (2020) reported findings from a comprehensive meta-analysis of individual data from all known randomized trials. Five trials were identified, 4 randomized studies enrolling 801 participants for all endpoints of interest, and for peak VO_2 alone ($n = 60$), there was an additional single arm non-randomized trial (FIX-HF-5C2) with a prospective comparison of its 24 week peak VO_2 data compared with the FIX-HF-5C control group. Pooled analysis showed that, compared with control, CCM significantly improved peak VO_2 (mean difference +0.93, 95% CI 0.56 to 1.30 mL/kg/min, $P < 0.00001$), 6 min walk test distance (mean difference +17.97, 95% CI 5.48 to 30.46 m, $P = 0.005$), and quality of life measured by MLWHFQ (mean difference -7.85, 95% CI -10.76 to -4.94, $P < 0.00001$). As a sensitivity analysis, we excluded the FIX-HF-5C2 trial (only relevant for peak VO_2), and the result was similar, mean difference +0.65, 95% CI 0.21 to 1.08 mL/kg/min, $P = 0.004$.

The authors concluded that CCM has emerged as a promising device treatment for heart failure in individuals not well suited for cardiac resynchronization therapy; However larger, well-conducted RCTs using a parallel double-blind design are needed in order to determine the effect of CCM on major mortality and morbidity outcomes before CCM can be widely recommended as an effective treatment option for individuals with heart failure.

Li et al (2024) discussed the potential and challenges of enhancing myocardial function with cardiac contractility modulation devices. Review of recent meta-analyses and clinical trials demonstrated that while CCM may not be associated with reduced cardiovascular adverse events, it does result in significant improvements in cardiopulmonary function and capacity, making it a potential alternative treatment for individuals with advanced heart failure (Abraham et al [2018]; Fastner et al [2021]; Liu et al [2017]; Nadeem et al [2020]). Some studies have observed improvements in quality of life and functional status (Linde et al [2022]) but no significant differences in 6-minute walk distances, arrhythmic events, hospitalizations, or mortality were noted (Mando et al [2019]). Electrophysiologists and device clinic staff will need training in the implantation, analysis, evaluation, and optimization of CCM devices, however due to similarities with other cardiac modalities, these could all be straightforward. This technology is viewed as a more holistic approach to patient management and a promising area for ongoing research. Authors determined that despite its potential, CCM therapy still has some limitations to overcome. Currently, there is no concrete evidence that CCM reduces mortality or hospitalization rates for individuals with heart failure (Kleemann [2015]). The exact effects of the procedure on the different patient groups continues to be a gap in knowledge. No studies have been conducted on the effects of the procedure on the development of right ventricular failure and diastolic hypertension. The follow-up time for CCM treatment effects has been relatively short, and there is a lack of randomized control groups. Studies on combination therapies and long-term use are also limited. The relationship between atrial fibrillation burden and CCM device implantation has not been explored. Authors determined that future studies could improve treatment outcomes and expand the beneficiary population by combining CCM with multiple treatment regimens. Further large-scale randomized controlled trials are needed to confirm the long-term benefits of CCM therapy.

Hayes released a health technology assessment (2024) and found existing evidence to be low-quality with mixed findings and inconsistent. Two studies found no statistically significant difference in changes in left ventricular ejection fraction (LVEF) or peak maximal oxygen uptake (VO_2) between CCM plus OMT and OMT alone. Evidence provided by 4 RCTs suggested that CCM therapy has no significant impact on survival up to 1 year post-implantation. Nine studies were found to be inconclusive regarding the independent effect of CCM on improvements in NYHA functional class. Quality of life was evaluated in 9 studies and was measured by the Minnesota Living with Heart Failure Questionnaire (MLWHFQ). Information was found to be conflicting. In 3 of the 4 RCTs, CCM therapy was associated with a statistically significantly greater improvement in MLWHFQ than OMT alone, whereas the fourth trial found no differences in quality of life (QOL) between individuals treated with CCM plus OMT compared with OMT alone. One study favored cardiac resynchronization therapy over CCM in improvements in QOL. Of 5 studies statistically evaluating changes from baseline, 3 reported a statistically significant improvement from baseline and 2 reported that improvement were not statistically significantly different. In 6 studies, evidence was inconsistent regarding the effect of CCM on the Six-Minute Hall Walk Test. One study reported a mean clinically significant improvement. Changes in 4 other studies did not achieve clinical significance and 1 study only presented graphical data so clinical significance could not be assessed. Serious adverse events were monitored in 9 of the eligible studies. Serious adverse events included lead dislodgement, CCM pocket infection, pericardial effusion, inappropriate implantable cardioverter defibrillator (ICD) firing, lead fracture, lead perforation, pocket dehiscence, pocket stimulation, pocket bleeding, sensation due to CCM, extracardiac stimulation, general malfunction of the CCM device, deep vein thrombosis, pocket erosion

requiring replacement of pacemaker leads, supraventricular arrhythmias, and worsening HF. Reviewers determined that additional, well-designed comparative studies with sufficient follow-up duration are needed to determine whether CCM with the Optimizer Smart System is safe, more effective than OMT alone, and has durability of benefit.

Supplemental Information

American College of Cardiology

In 2023, the ACC published Expert Consensus Decision Pathway on Management of Heart Failure with Preserved Ejection Fraction. They state that “Other device interventions for HFpEF such as.... or cardiac contractility modulation are under evaluation; their benefits remain ambiguous. Such procedures should be considered only within the context of clinical trials.”

The updated ACC Decision Pathway (2024) for the treatment of HF does not include recommendations for use of cardiac contractility modulation therapy as a treatment for HF.

American Heart Association/American College of Cardiology/Heart Failure Society of American

The 2022 American Heart Association (AHA)/American College of Cardiology (ACC)/Heart Failure Society of America (HFSA) Guideline for the Management of Heart Failure does not include recommendations for use of cardiac contractility modulation therapy as a treatment for HF.

European Society of Cardiology

In 2021, the European Society of Cardiology (ESC) guidelines for the diagnosis and treatment of acute and chronic heart failure listed CCM as a device under evaluation for individuals with NYHA class III-IV HF. The committee concluded that the device was associated with small improvement in exercise tolerance and quality of life. The 2023 focused update of the ESC guidelines do not mention the use of CCM.

National Institute for Health and Care Excellence (NICE)

In June 2019, NICE published guidelines for cardiac contractility modulation device implantation for heart failure. They state:

- “The evidence on cardiac contractility modulation device implantation for heart failure 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.”
- “Further research should ideally be in the form of randomized controlled trials....”

Clinical Trials which may influence future determinations:

NCT	Title	N	Estimated Date of Completion
NCT03970343	Post Approval Study (PAS) of the OPTIMIZER Smart and CCM Therapy (PAS)	620	July 2028
NCT05064709	Assessment of CCM in HF With Higher Ejection Fraction (AIM HIGHer)	1500	Feb 2029
NCT05855135	Assessment of Combined CCM and ICD Device in HFrEF (INTEGRA-D)	300	July 2027

Regulatory Status

The Optimizer Smart System (Impulse Dynamics, Inc) received U.S. Food and Drug Administration premarket approval in 2019 (P180036). The Optimizer is intended to improve 6-minute hall walk distance, quality of life, and functional status of NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy, who are in normal sinus rhythm, are not indicated for Cardiac Resynchronization Therapy, and have a left ventricular ejection fraction ranging from 25% to 45%.

The OPTIMIZER Smart system is comprised of the following components:

- OPTIMIZER Smart Implantable Pulse Generator
- Commercially Available IS-1 Active Fixation Bipolar Pacing Leads
- OPTIMIZER Mini Charger
- OMNI II Programmer with OMNI SMART Software
- OPTIMIZER System Lead Extension Cable (Optional)

In October 2021, the FDA approved a modification to the labeling for Optimizer Smart Medical Devices, allowing the removal of “normal sinus rhythm” from the indications statement. (P180036, supplement S008)

In February 2024, the FDA initiated a Class 2 Device Recall for OPTIMIZER Smart Mini and OPTIMIZER Lite. It was determined that due to software design OPTIMIZER devices may cease to deliver CCM therapy if the device incorrectly detects a charging error. This may cause patients to experience heart failure symptoms similar to before implantation of the device. The firm recommends all patients with implant card showing model CCM X11, who have experienced the "A9" charge error, charge their implanted device to no more than 75% of full capacity to circumvent the issue. The firm is working on a software update to address this issue. Summary of the safety communication can be found online: <https://impulse-dynamics.com/safety-information/>.

Product code: QFV

Government Regulations

National:

MLN Matters (MM14311): **Cardiac Contractility Modulation for Heart Failure**. Released: Dec 19, 2025

CCM treats heart failure (HF). Effective October 28, 2025, CMS covers CCM for treating HF under CED according to the coverage criteria we outline in the Medicare National Coverage Determination (NCD) Manual, Chapter 1, section 20.39.

Consistent with section 1142 of the Social Security Act, the Agency for Healthcare Research and Quality supports clinical research studies that we determine meet all the criteria and standards in NCD 20.39.

We don't cover CCM for HF for patients outside of a CMS-approved study. See NCD 20.39 for the complete coverage criteria.

Note: Nothing in the NCD would preclude coverage of CCM through NCD 310.1 — Clinical Trial Policy or through the investigational device exemption policy.

Local:

No determination noted on cardiac contractility modulation.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting
- Leadless Cardiac Pacemakers

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 1/21/26, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/25	2/25/25		• Joint policy established • Replacing IMP: Cardiac Contractility Modulation Therapy (i.e., Optimizer Smart) for the treatment of Heart Failure
5/1/26	2/17/26		• Routine maintenance (slp) • Policy reformatted • MPS updated to current language

Next Review Date: 1st Qtr, 2027

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CARDIAC CONTRACTILITY MODULATION (I.E., OPTIMIZER SMART) FOR THE
TREATMENT OF HEART FAILURE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to Government Regulation section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.