KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Cardiac Contractility Modulation Device

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Kaiser Permanente Medical Policy	Due to the absence of Medicare (CMS or MACs) coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Cardiac Contractility Modulation Device"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Kaiser Interregional New Technologies Committee Assessment
Date: 04/27/2020

There is insufficient evidence regarding the efficacy and safety of Optimizer (cardiac contractility modulation [CCM]) as compared to optimal medical management for heart failure.

Based on the review of 4 randomized trials (n=801) that compared Optimizer CCM plus optimal medical therapy (OMT) versus OMT alone, there is moderate-quality evidence that treatment of heart failure with

Optimizer CCM is associated with short-term improvements in quality of life and peak Vo_2; however, findings for other symptom-related outcomes were mixed and there is a lack of long-term outcomes, including hospitalization and mortality data. Thus, the existing evidence regarding how Optimizer CCM effectively manages heart failure is of insufficient quantity and/or quality.

Heart failure (HF), also referred to as congestive HF, is a chronic, progressive condition that develops due to circumstances that overwork and damage the heart, rendering the heart muscle unable to pump enough blood to meet the body's needs for blood and oxygen. The primary causes of HF include coronary heart disease, high blood pressure, and diabetes. Approximately half of heart failure cases are associated with a reduced ejection fraction (HFrEF), typically defined as a left ventricular ejection fraction (LVEF) <35% or <40%. The impact of heart failure on patient quality of life as well as its economic costs are substantial.

Treatment of HF is focused on symptom relief and typically includes lifestyle modification and oral medications that treat underling conditions including hypertension, high cholesterol, diabetes, and obesity. Treatment options for patients with severe HFrEF with inadequate response to medications include cardiac resynchronization therapy (CRT), left ventricular assist devices (LVAD), and heart transplantation. However, many patients with moderate to severe HF symptoms—including the 25% to 35% of patients who have HFrEF categorized as NYHA functional class III—do not meet established indications for these options. The Optimizer Smart System (Impulse Dynamics, Inc., Orangeburg, NY, USA) is intended for patients in this treatment "gap."

The Optimizer Smart System is a pacemaker-sized, rechargeable, implanted device intended to deliver cardiac contractility modulation (CCM) therapy to increase the strength of the heart's ventricular contraction in patients with stage III to IV HF whose LVEF is 25% to 45% despite optimal medical therapy (OMT).

The following clinical question was the subject of the review:

What is the efficacy and safety of the Optimizer Smart System for treatment of heart failure?

A comprehensive search was conducted on March 18, 2020 to identify systematic reviews, technology assessments, and randomized trials addressing the clinical question.

Based on the existing literature:

- The body of evidence on the use of Optimizer CCM for treatment of heart failure consists of 4 randomized trials (n=801) that compared Optimizer CCM plus optimal medical therapy (OMT) versus OMT alone.
- Two early trials employed a sham-control group (FIX-HF-5 Pilot) and a crossover design (FIX-CHF-4), while the 2 more recent trials used a more traditional design. The sham-controlled and crossover trials noted significant placebo effects for several outcomes.
- Moderate-quality evidence suggests that Optimizer CCM plus OMT results in clinically and statistically significant improvements in short-term clinical outcomes including QOL and peak Vo_2 compared to OMT alone.
- It is unclear if Optimizer CCM has an impact on 6-minute hall-walk (6MHW) distance, NYHA class, ventilatory threshold, hospitalizations, or mortality. The quality of evidence for these outcomes was low due to mixed findings, a lack of between-group differences, insufficient power, and/or inadequate duration of follow-up.
- Moderate-quality evidence suggests that rates of serious adverse events were relatively low and similar between CCM and OMT groups. The implantation procedure and short-term use of the device appear to be relatively safe and comparable to similar interventions (e.g., pacemakers).

- The Optimizer CCM implantation procedure takes about 3 hours to complete, although there was considerable variation across patients and the quality of this evidence is low.
- The main limitations of the included trials are their relatively small sample sizes (801 patients total), lack of long-term follow-up, mixed findings for several key outcome measures (e.g., 6MHW, NYHA class), and lack of a sham control for the 2 most recent trials.
- These promising but preliminary findings suggest that Optimizer CCM is a safe and effective treatment for patients with NYHA class III heart failure with ejection fraction between 25% and 45%. Additional randomized trials are needed to confirm these initial findings and evaluate long-term outcomes.

Among several relevant clinical practice guidelines identified in the evidence search, the European Society of Cardiology (2016) notes that CCM may be considered in selected patients with HF, and NICE (2019) notes that although there are no major safety concerns, the device should only be used in research settings due to the lack of evidence on efficacy.

The committee discussed uncertainty regarding benefits of Optimizer CCM beyond symptomatic improvement. In particular, there is a lack of mortality data. Given the determination of "insufficient evidence," the plan is to continue participation in clinical trials and to await publication of mortality data prior to considering adopting this technology.

Applicable Codes

Considered Not Medically Necessary:

CPT® Codes	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
HCPC Codes	**Description**

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

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
04/07/2020	04/06/2021[MPC], 04/05/2022[MPC], 04/04/2023[MPC], 06/04/2024MPC, 06/03/2025[MPC]	10/26/2022

[MPC] Medical Policy Committee

Revision History	Description
04/07/2020	MPC approved to adopt new non-coverage criteria (Medicare's position)
05/26/2020	Added background from INTC review on 4/27/2020
10/26/2022	Updated applicable codes, including new codes released 01/01/22 and 04/01/22.