FirstChoice VIP CARE
by Select Health of South Carolina

# Cardiac contractility modulation

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Recent review date: 6/2025

Next review date: 10/2026

Policy contains: Cardiac contractility modulation; chronic heart failure.

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## Coverage policy

The Implantable Optimizer® Smart System for delivering Cardiac Contractility Modulation™ (Impulse Dynamics, Orangeburg, New York) for treating moderate to severe chronic heart failure is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Cardiac resynchronization therapy.
- Drug treatment.
- Heart transplant or other surgical intervention.

## Background

Heart failure occurs from an inability of the heart to pump sufficient blood and oxygen to support various body organs. About 6.2 million U.S. adults have heart failure, which was mentioned on 379,800 (13.4%) of all 2018 death certificates (Centers for Disease Control and Prevention, 2023).

The New York Heart Association classifies heart failure into four classes, based on degree of ability to function, with Class IV being the most severe. These definitions include (American Heart Association, 2023):

- Class I — No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).
- Class II — Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).
- Class III — Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.
- Class IV — Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.

Recent improvements in therapy for heart failure with reduced ejection fractions have reduced morbidity and mortality. However, only one-third of patients meet criteria for an implantable defibrillator (left ventricle ejection fraction ≤ 35%) and for cardiac resynchronization therapy (QRS ≥ 130 milliseconds and evidence of left bundle branch block), and symptoms fail to improve in many patients who do meet criteria (Cappannoli, 2021). The five-year survival rate for heart failure patients with reduced ejection fraction has remained steady in the past several decades at about 50% (Giallauria, 2020).

Cardiac Contractility Modulation works through an electrical pulse delivered during the absolute refractory period, just after the heart contracts. In contrast to a pacemaker or defibrillator, Cardiac Contractility Modulation modulates the strength of heart muscle contraction, instead of rhythm. The device is implanted in the right or left pectoral region and is connected to two standard pacemaker leads threaded through veins into the right ventricle, which sense ventricular activity and deliver cardiac contractility modulation signals. An optional additional lead may be used to sense atrial activity (usually placed in the right atrial appendage). Pulses are delivered at regular intervals throughout the day that increase cardiac output or myocardial contractility (Impulse Dynamics, 2018).

On March 21, 2019, the U.S. Food and Drug Administration granted premarket application approval to Impulse Dynamics for the Optimizer Smart System for treatment of patients with New York Heart Association Class III or IV heart failure who remain symptomatic after medical therapy, are in normal sinus rhythm, are not candidates for cardiac resynchronization therapy, and have a left ventricular ejection fraction from 25% to 45%. Potential improvement measures include six-minute hall walk distance, quality of life, and functional status. Patients for whom the device is contraindicated include those: 1) with permanent or long-standing persistent atrial fibrillation or flutter; 2) with a mechanical tricuspid valve; and/or 3) for whom vascular access for implantation of the leads cannot be obtained (U.S. Food and Drug Administration, 2019).

On October 6, 2021, the U.S. Food and Drug Administration (2021) approved removal of the normal sinus rhythm requirement from the indications.

## Findings

An updated guideline on heart failure from the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines mentioned cardiac contractility modulation as an implantable electrical intervention but made no specific recommendation for or against its use. They cited evidence from four randomized controlled trials of participants with primarily Class III heart failure that showed benefits in exercise capacity and quality of life but not in death or hospitalizations (Heidenreich, 2022).

A guideline from the United Kingdom found insufficient evidence supporting use of cardiac contractility modulation for heart failure, suggesting that the technique may be better for patients with less severe heart failure, even though tests to date have only included Class III and IV patients. The procedure should only be used in the context of research (National Institute for Health and Care Excellence, 2019).

A European Cardiac Society consensus opinion states cardiac contractility modulation may be considered in patients with a left ventricular ejection fraction of 25% to 45%, and a narrow QRS complex < 130 milliseconds to improve exercise capacity, quality of life, and alleviate heart failure function (Seferovic, 2019).

The American College of Cardiology, American Heart Association, and other major cardiovascular societies addressed cardiac contractility modulation following formal evidence review and expert panel rating process. The resulting recommendation rated cardiac contractility modulation as "may be appropriate" for patients meeting specific criteria, namely New York heart association class II-IV heart failure, left ventricular ejection fraction between 25-45%, narrow QRS duration (<130 ms), who remain symptomatic despite guideline-directed medical therapy and are not candidates for Cardiac Resynchronization Therapy (Russo, 2025). This rating was based on the panel's assessment of available evidence, which indicated benefits in quality of life, symptoms, and exercise capacity, but lacked sufficient data demonstrating reductions in mortality or heart failure hospitalizations (Russo, 2025). According to the appropriate use criteria methodology, a "may be appropriate" rating signifies that, given the recognized limitations in evidence for major clinical outcomes, the therapy may still be considered a reasonable clinical option for appropriately selected patients based on potential symptomatic benefits and clinical judgment (Russo, 2025).

A randomized controlled trial (n = 160) that led to U.S. Food and Drug Administration approval compared participants with heart failure given optimal medical treatment with versus without cardiac contractility modulation. After 24 weeks, the group with modulation showed superior improvements in Minnesota Living with Heart Failure questionnaire ($P < .001$), New York Hospital Association functional class ($P < .001$), and six-minute hall walk distance ($P = .02$). The composite rate of cardiovascular death and heart failure hospitalizations declined from 10.8% to 2.9% ($P = .048$) (Abraham, 2018).

A review of 475 hospitalized patients with heart failure in the United Kingdom documents that only 24 (5.1%) meet criteria for cardiac contractility modulation (ejection fraction 25% to 45%, QRS duration < 130 milliseconds, New York Heart Association class III and IV, and treated for heart failure > 90 days on stable medications). Exclusion criteria included significant valvular disease, permanent or persistent atrial fibrillation, biventricular pacing system implanted or QRS duration > 130 milliseconds, and patients not suitable for device therapy due to palliative treatment intent. Heart failure patients with atrial fibrillation represent an additional 3.8% (Dulai, 2021).

Results of the following systematic reviews and meta-analyses cite insufficient data supporting reduced mortality, arrhythmic events, or hospitalization rates, or improvement in 6-minute walking distance, although significant short-term improvements in cardiopulmonary function and capacity and quality of life were observed. While potential indications for cardiac contractility modulation are expanding from initially treating patients with sinus rhythm and narrow QRS on optimal medical therapy to treating those with atrial fibrillation or wide QRS not responding to cardiac resynchronization therapy, larger randomized controlled trials with longer follow-up are needed to determine who would most benefit from the intervention prior to widespread use.

A systematic review/meta-analysis of four randomized controlled trials (n = 801) analyzed the outcomes of participants receiving standard of care with and without the Optimizer device. After a mean follow up of six months, those with cardiac contractility modulation had superior Minnesota Living with Heart Failure Questionnaire results ($P = .0008$). The study found no differences between groups in heart failure hospitalizations ($P = .12$), all-cause hospitalizations ($P = .33$), six-minute walk distance ($P = .10$), arrhythmias ($P = .14$), pacemaker and implantable cardioverter defibrillator malfunctions ($P = .06$), or all-cause mortality ($P = .92$). Authors state larger trials with longer follow up may be needed to determine benefits of this therapy (Mando, 2019).

A meta-analysis of five controlled trials (n = 861) of cardiac contractility modulation for heart failure revealed superior outcomes after six months for cases versus controls for peak oxygen consumption ($P < .00001$), six-

minute walk test distance ($P$ = .005), and Minnesota Living with Heart Failure Questionnaire scores ($P$ < .00001). Authors state low average patient age in the four largest trials (52, 58, 59, and 63) is a limitation. One author acknowledged receiving honoraria and lecture fees from Impulse Dynamics (Giallauria, 2020).

A meta-analysis of four trials (n = 723) found that cardiac contractility modulation did not significantly improve all-cause mortality or all-cause hospitalizations. The study found no differences in the rate of adverse effects among patients given this treatment, compared with sham or usual care. Significant improvements were observed in peak oxygen consumption ($P$ = .006) and the six-minute walk test distance ($P$ = .049) (Liu, 2017).

In 2023, we added a guideline from the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines (Heidenreich, 2022). The current evidence fails to demonstrate a positive benefit on long-term outcomes and survival, and no policy changes are warranted.

In 2024, we deleted old references and found no newly published, relevant literature to add to the policy. No policy changes are warranted.

In 2025, we added findings from expert panel of various medical societies (Russo, 2025). No policy changes were warranted.

## References

On April 4, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Cardiac Contractility Modulation” and “chronic heart failure.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.


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## Policy updates

5/2021: initial review date and clinical policy effective date: 6/2021.

5/2022: Policy references updated.

5/2023: Policy references updated.

5/2024: Policy references updated.

5/2025: Policy references updated.