CLINICAL MEDICAL POLICY	
Policy Name:	Cardiac Contractility Modulation (CCM) Therapy
Policy Number:	MP-114-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	11/01/2025; 11/01/2024; 11/01/2023; 11/01/2022
Effective Date:	12/01/2025; 12/01/2024; 12/01/2023; 12/01/222
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Revision Date:	09/17/2025; 09/18/2024; 09/20/2023; 09/21/2022
Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 9

Policy History

Date	Action
12/01/2025	Provider Effective date
10/14/2025	PARP Approval
09/17/2025	QI/UM Committee review
09/17/2025	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
12/01/2024	Provider Effective date
10/07/2024	PARP Approval
09/18/2024	QI/UM Committee review
09/18/2024	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
12/01/2023	Provider Effective date
10/11/2023	PARP Approval
09/20/2023	QI/UM Committee review
09/20/2023	Annual Review: Removed "Normal sinus rhythm" requirement from clinical criteria, per FDA guidance. Updated 'Summary of Literature' and 'Reference Sources' sections.
12/01/2022	Provider Effective date
10/05/2022	PARP Approval
09/21/2022	QI/UM Committee review
09/21/2022	Policy initially developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary cardiac contractility modulation therapy.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) - A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Cardiac Contractility Modulation (CCM) - a device-based therapy for heart failure (HF) that involves applying 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.

QRS complex - includes the Q wave, R wave, and S wave. The QRS complex represents the electrical impulse as it spreads through the ventricles and indicates ventricular depolarization.

Procedures

Program Exception
CCM therapy requires a Program Exception. The ordering healthcare provider must provide a supporting statement indicating why the requested therapy is medically necessary, and all other options have been or are likely to be ineffective, adversely affect patient compliance, or cause an adverse reaction.

1. Cardiac contractility modulation (CCM) therapy is considered medically necessary when ALL of the following conditions are met:
    A. The individual is diagnosed with a New York Heart Association (NYHA) classification of heart failure III (see *Informational* section below); AND
    B. Remains symptomatic despite optimal medical therapy (OMT); AND
    C. Left ventricular ejection fraction ranging from 25-45%; AND

D. The individual is not considered a candidate for Cardiac Resynchronization Therapy (CRT); AND
E. The individual's QRS duration greater than or equal to 150 msec.

2. Contraindications
   The use of a CCM therapy device is contraindicated under the following conditions:
   - Individuals with mechanical tricuspid valve
   - Individuals in whom vascular access for implantation of the leads cannot be obtained

3. CCM therapy services are not covered for any other conditions other than those listed above because the scientific evidence has not been established. These services will deny as not medically necessary.

4. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

5. Place of Service
   The proper place of service for insertion and/or removal of the CCM device may either be in the outpatient or inpatient sector.

Governing Bodies Approval

On March 21, 2019, the FDA issued an approval to Impulse Dynamics, developer of the implantable Optimizer® Smart System for delivering CCM therapy.

As of October 26, 2021, the FDA approved a modification of labeling for Impulse Dynamics Optimizer Smart medical device, allowing the removal of "normal sinus rhythm" (NSR) from the indications for use statement. Since patients are no longer required to be in NSR at the time of Optimizer implant, heart rhythm does not impose any restrictions on patients eligible for Optimizer implant, thereby vastly increasing the number of patients who can be treated with CCM therapy.

CMS
The Centers for Medicare and Medicaid Services (CMS) has not issued any guidance regarding CCM therapy.

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

As of May 2022, the TAG workgroup assigned CCM therapy an Option # 3, specifically for CPT codes 0408T, 0411T, and 0418T.

Program Exception
CCM therapy requires a Program Exception. The ordering physician must provide a supporting statement indicating why the requested therapy is medically necessary, and the alternative options have been or are likely to be ineffective, adversely affect patient compliance, or cause an adverse reaction.

Summary of Literature

Heart disease is currently listed as the leading cause of death in men, women, and people of most racial and ethnic backgrounds in the United States (CDC, 2022). Treatment for heart disease varies depending on the severity of the condition, the stage and type of heart failure, underlying conditions and the individual patient. Treatments may include lifestyle changes, medications, or surgical treatments (Johns Hopkins, 2022). Heart failure's various disease subcategories have been identified over the years, and the latest guidelines differentiate clinical entities according to left ventricular ejection fraction (heart failure with reduced, mid-range or preserved ejection fraction [HFrEF]), time-course of the disease (acute or chronic) and symptomatic severity (New York Heart Association (NYHA) class) (Giallauria, Parlato, Di Lorenzo, et al., 2021).

Medical devices have become a significant part of guideline directed therapies for HFrEF. Implantable cardioverters-defibrillators (ICDs) and cardiac resynchronization therapy (CRT) have a clear role in therapy with very specific indications: ICDs are recommended for prevention of sudden death in patients with ischemic or dilated cardiomyopathy (with some limitations), while CRT is indicated for patients with an intraventricular conduction delay (QRS > 130 ms) and the recommendation is stronger in case of a left bundle branch block (LBBB) morphology. However, CRT indications may leave many patients ineligible, including patients with medically refractory disease without intraventricular conduction delay. It has also been shown in studies that there are a proportion of patients that, after CRT implantation, showed no benefit and are considered non-responders (ranging from 20 to 40% of implanted patients according to different studies) This gap is coverage is where cardiac contractility modulation (CCM) plays a pivotal role (Giallauria, Parlato, Di Lorenzo, et al., 2021).

CCM therapy may help to treat heart failure when patients are under a proper treatment plan but still experience heart failure symptoms. The device-based therapy uses multiple electrodes to improve a patient's heart failure symptoms, exercise capacity, and overall quality of life (Giallauria, Parlato, Di Lorenzo, et al., 2021). CCM delivered by the Optimizer IV is an established device that is of benefit to patients with symptomatic heart failure, on OMT, and with normal or mildly prolonged QRS duration, thus providing support for the large complement of heart failure patients who do not have an indication for CRT. CCM delivers a biphasic high-voltage signal (7.5 V/22-ms duration) to the right ventricular septum during the absolute refractory period. When administered for 5–12 hours/day, this device acutely augments dP/dt without raising oxygen consumption, thereby improving cardiac efficiency. Improvements have been seen in patients with normal or slightly prolonged QRS durations. Similar to CRT, CCM may provide even greater improvement in patients with less severe EF (>25 %) (Abi-Samra, Gutterman, 2016).

The implantation of the CCM device is best performed under moderate sedation in an OR grade sterile environment with fluoroscopic guidance. Once the device is implanted, noninvasive testing is then

performed to ensure proper connectivity, sensing, and appropriately timed delivery (Abi-Samra, Gutterman, 2016). The device delivers electrical impulses delivered during the absolute refractory period (ARP) of the action potential, around 30ms after onset of QRS complex. It incorporates biphasic, bipolar signals administered for a duration of 20ms, with energy levels that are 50-100 fold that of a standard pacemaker impulse. They are typically administered for 5-12 hours on a daily basis. The shorter duration appears comparable in effectiveness, is more efficacious in reducing battery drain and enables eligibility of individuals with frequent ectopy burden who may otherwise be excluded (Patel, 2020).

Rationale

A randomized prospective study was performed to compare patients treated with guideline-directed optimal medical therapy (including an implanted cardiac defibrillator, when indicated) with those treated with optimal medical therapy plus CCM. The earliest of these, the FIX-HF-4 study, which was conducted in European Union, showed that 3 months of CCM treatment improved exercise tolerance and quality of life in subjects. A number of real-world registry studies have shown that CCM-mediated improvements in symptoms, exercise tolerance, and quality of life are sustained through 2 years of follow-up.5 They have also shown that patients with EF between 35% and 45% have even greater clinical improvements than those with LVEF <35% and that for all patients CCM reduces the rate of HF hospitalizations compared with the year before treatment (Borggrefe, Mann, 2018).

A prospective blinded randomized trial enrolled 48 patients. Eligible subjects had symptoms despite optimal HF medications, left ventricular ejection fraction <40% and peakVO2 ≥ 9 ml O2/kg/min. All patients received a CCM system with two ventricular leads and were randomized to CCM active through both or just one ventricular lead; 25 patients were randomized to receive signal delivery through two leads (Group A) and 23 patients to signal delivery through one lead (Group B). The study compared the mean changes from baseline to 6 months follow-up in peakVO2, NYHA classification, and quality of life. Following 6 months, similar and significant ($p < 0.05$) improvements from baseline in NYHA (−0.7 ± 0.5 vs. −0.9 ± 0.7) and MLWHFQ (−14 ± 20 vs. −16 ± 22) were observed in Group A and in Group B. PeakVO2 showed improvement trends in both groups (0.34 ± 1.52 vs. 0.10 ± 2.21 ml/kg/min; p = ns). No patient died. Serious adverse event rates (20 events in 10 subjects) were not different between groups. No statistically significant difference was found in any of the study endpoints. The efficacy and safety of CCM in this study were similar when the signal was delivered through either one or two ventricular leads. These results support the potential use of a single ventricular lead for delivery of CCM (Röger, Said, Kloppe, 2017).

Defining potential responders and non-responders to CCM therapy is crucial for optimal decision-making and more data is needed in order to establish which patients are most likely to benefit from device implantation. Management algorithms have been proposed by several authors based on available evidence, but many grey zones still exist and the effect of CCM in some patients, like those with a right bundle branch block or patients that stay symptomatic after CRT implantation, still remains to be elucidated (Patel, 2022).

The American College of Cardiology and the American Heart Association has provided the following four stages of heart failure:

- **Stage A:** At risk for heart failure – People who are at risk for heart failure but do not yet have symptoms or structural or functional heart disease. Risk factors for people in this stage include hypertension, coronary vascular disease, diabetes, obesity, exposure to cardiotoxic agents, genetic variants for cardiomyopathy and family history of cardiomyopathy.

- **Stage B**: Pre-heart failure – People with current or previous symptoms of heart failure but with either structural heart disease, increased filling pressures in the heart or other risk factors.
- **Stage C:** Symptomatic heart failure – People with current or previous symptoms of heart failure.
- **Stage D**: Advanced heart failure – People with heart failure symptoms that interfere with daily life functions or lead to repeated hospitalizations.

Coding Requirements

Procedure Codes

CPT/HCPCS 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

* *Requires a Program Exception, with approval by a Medical Director on a case-by-case basis.*

Diagnosis Codes

ICD-10 Code	Description
I50.1	Left ventricular failure, unspecified
I50.20	Unspecified systolic (congestive) heart failure
I50.21	Acute systolic (congestive) heart failure
I50.22	Chronic systolic (congestive) heart failure
I50.23	Acute on chronic systolic (congestive) heart failure
I50.30	Unspecified diastolic (congestive) heart failure
I50.31	Acute diastolic (congestive) heart failure
I50.32	Chronic diastolic (congestive) heart failure
I50.33	Acute on chronic diastolic (congestive) heart failure
I50.40	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41	Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42	Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43	Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810	Right heart failure, unspecified
I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.89	Other heart failure

Informational

New York Heart Association (NYHA) Classification of Heart Failure

NYHA Class	Definition	Limitation	Example
I	Ordinary physical activity does not cause undue fatigue, dyspnea, or palpitations.	None	Can complete any activity requiring ≤ 7 MET: • Carry 11 kg up 8 steps • Carry objects weighing 36 kg • Shovel snow • Spade soil • Ski • Play squash, handball, or basketball • Jog or walk 8 km/hour
II	Ordinary physical activity causes fatigue, dyspnea, palpitations, or angina.	Mild	Can complete any activity requiring ≤ 5 MET: • Garden

			• Roller skate • Walk 7 km/hour on level ground • Climb one flight of stairs at a normal pace without symptoms
III	Comfortable at rest; less than ordinary physical activity causes fatigue, dyspnea, palpitations, or angina.	Moderate	Can complete any activity requiring ≤ 2 MET: • Shower or dress without stopping • Strip and make a bed • Clean windows • Play golf • Walk 4 km/hour
IV	Symptoms occur at rest; any physical activity increases discomfort.	Severe	Cannot do or cannot complete any activity requiring ≥ 2 MET; cannot do any of the above activities

MET = metabolic equivalent of task, a measure of how much energy is expended compared to remaining at rest (Merck, 2022)

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

Reference Sources

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