02.02.17 Cardiac Contractility Modulation Therapy Device Components and Ancillary Services

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Original Effective Date: January 2016

Review Date: November 2025

Revised: June 2025

DISCLAIMER/INSTRUCTIONS FOR USE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Related Policies:

- 02.02.19 Baroreflex Stimulation Device Components and Ancillary Services
- 02.02.22 Noninvasive Heart Failure and Arrhythmia Management and Monitoring System

Summary

Description

Note: This Wellmark medical policy is NOT an evidence review for the implantation or replacement of a cardiac contractility modulation therapy (0408T), but rather a supplemental coverage policy for Cardiac Contractility Modulation components and ancillary services (0410T-0418T, 0948T-0949T, C1824 & K1030).

Refer to Wellmark Authorization Table for the prior approvement requirements and the applicable EviCore Evidence-based Guideline regarding the implantation or replacement of cardiac contractility modulation therapy (0408T).

The use of cardiac contractility modulation (CCM) therapy has been proposed as a treatment option for individuals with chronic moderate-to-severe heart failure (HF).

Additional Information
None

OBJECTIVE

The objective of this medical policy is a supplemental coverage policy for Cardiac Contractility Modulation components and ancillary services (0410T-0418T, 0948T-0949T, C1824 & K1030).

PRIOR APPROVAL

Not applicable.

POLICY

Note: This Wellmark medical policy is NOT an evidence review for the implantation or replacement of a cardiac contractility modulation therapy (0408T), but rather a supplemental coverage policy for Cardiac Contractility Modulation components and ancillary services (0410T-0418T, 0948T-0949T, C1824 & K1030).

Refer to Wellmark Authorization Table for the prior approvement requirements and the applicable EviCore Evidence-based Guideline regarding the implantation or replacement of cardiac contractility modulation therapy (0408T).

The use of Cardiac Contractility Modulation components and ancillary services (0410T-0418T, 0948T-0949T, C1824 & K1030) are also considered **investigational** for all indications, including but not limited to heart failure because the primary procedure of implantation or replacement of cardiac contractility modulation (0408T) is considered investigational per the applicable EviCore evidence-based Guideline.

POLICY GUIDELINES

Coding
See the Codes table for details.

BACKGROUND

Chronic Heart Failure
Heart failure (HF) is a chronic condition that develops over time due to circumstances that overwork and damage the heart. Primary causes of HF include coronary heart disease, high blood pressure and diabetes. HF is characterized by the inability of the heart to pump blood efficiently.

Management
Heart failure is not curable, but can be managed with lifestyle changes (diet, exercise, quitting smoking and drinking and weight loss), various medications, surgical treatments (implantable cardioverter

defibrillator, cardiac resynchronization therapy (CRT), left ventricular assist device or heart transplant) and ongoing monitoring to prolong and improve quality of life (QOL).

Medications may include the following:

- Angiotensin-converting enzyme (ACE) inhibitors
- Aldosterone antagonists
- Angiotensin receptor blockers
- Beta-blockers
- Digoxin
- Diuretics
- Isosorbide dinitrate/hydralazine hydrochloride

Regulatory Status

In March 2019, the U.S. Food and Drug Administration (FDA) granted Impulse Dynamics breakthrough device exemption for the OPTIMIZER® Smart Implantable Pulse Generator (Impulse Dynamics, Orangeburg, NY), with approved use in the treatment of individuals with chronic, moderate-to-severe (New York Heart Failure [NYHA] Class III or ambulatory Class IV) heart failure (HF) who remain symptomatic despite guideline-directed medical therapy (GDMT). Recipients must be in normal sinus rhythm with left ventricular ejection fraction (LVEF) from 25 to 45 percent and not considered a candidate for cardiac resynchronization therapy (CRT) to restore normal heart rhythm. The OPTIMIZER Smart System treatment, referred to as cardiac contractility modulation (CCM), delivers electrical signals to the ventricles during the ventricular absolute refractory period. The expected result is improvement in 6-mintue hall walking distance, quality of life, functional status, and exercise tolerance.

On October 26, 2021, the FDA approved a modification of labeling for the Optimizer Smart medical device, allowing the removal of “normal sinus rhythm” (NSR) from the indications for use statement.

RATIONALE

Not applicable.

SUPPLEMENTAL INFORMATION

Not applicable.

REFERENCES

Not applicable.

CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		

Codes	Number	Description
	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
	0948T	Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation system with interim analysis, review and report(s) by a physician or other qualified health care professional
	0949T	Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation system, remote data acquisition(s), receipt of transmissions, technician review, technical support, and distribution of results
HCPCS		
	C1824	Generator, cardiac contractility modulation (implantable)
	K1030	External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only

Codes	Number	Description
Type of Service	Cardiology	
Place of Service	Inpatient/Outpatient	

POLICY HISTORY

Date	Reason	Action
November 2025	Interim Review	Policy Revised
July 2025	Annual Review	Policy Renewed
June 2025	Interim Review	Policy Revised
January 2025	Interim Review	Policy Revised
July 2024	Annual Review	Policy Renewed
July 2023	Annual Review	Policy Renewed
January 2023	Annual Review	Policy Revised
January 2021	Annual Review	Policy Revised
January 2020	Annual Review	Policy Revised
January 2019	Annual Review	Policy Revised
January 2018	Annual Review	Policy Revised
January 2017	Annual Review	Policy Revised
September 2016	Interim Review	Policy Revised
January 2016		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
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Des Moines, IA 50306-9232

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