Medicare Medical Policy

Cardiac Contractility Modulation for Heart Failure

MEDICARE MEDICAL POLICY NUMBER: 450

Effective Date: 11/1/2026

Last Review Date: 9/2026

Next Annual Review: 11/2026

MEDICARE COVERAGE CRITERIA 2
POLICY CROSS REFERENCES 2
POLICY GUIDELINES 3
REGULATORY STATUS 3
BILLING GUIDELINES AND CODING 4
REFERENCES 5
POLICY REVISION HISTORY 5

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Notes:

- This policy will address cardiac contractility modulation (CCM) systems only (e.g., the OPTIMIZER® Smart System by Impulse Dynamics or the Cardiac Contractility Modulation [CCM] System, by Optimizer Dynamic).
- Cardiac contractility modulation-defibrillator (CCM-D) systems, such as the OPTIMIZER® Integra CCM-D™ System, by Optimizer Dynamic, are out of scope for this policy.

Service	Medicare Guidelines
Cardiac Contractility Modulation (CCM) for Heart Failure (HF) Management	National Coverage Determination (NCD): Cardiac Contractility Modulation (CCM) for Heart Failure (HF) (20.39) **NOTES:** • NCD 20.39 criteria provides coverage of CCM when rendered in the context of the coverage with evidence development (CED) studies. Medicare-approved registries and clinical trials can be found on the Medicare CED Cardiac Contractility Modulation for Heart Failure web page. • In addition to the CED provision, the NCD states, "Nothing in this NCD would preclude coverage of CCM for HF management through… the Investigational Device Exemption (IDE) Policy." Therefore, MA plan coverage of these services may also be available if rendered in the context of a Medicare approved IDE study.

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to review for medical necessity, the following documentation **must** be provided. If any of these items are not submitted, the review may be delayed and the decision outcome could be affected:

- All clinical documentation pertinent to request in order to meet NCD criteria, including:
  - Condition to be treated;
  - Documentation that the patient meets the FDA market-authorized indications for use, with no contraindications for the device used; and
  - Documentation that the patient remains symptomatic despite at least 3 months of optimized guideline-directed medical therapy (GDMT)*; and
  - Confirmation the patient is under the care of a heart team;
- The name of the device that will be used; and,
- The NCT number for the registry or study the member or provider is enrolled in (enrollment is a requirement under the Medicare criteria).

*Patient management with GDMT and patient selection for CCM are critical to achieving the beneficial outcomes shown in the literature and should be under the care of a team who, together, can ensure that HF patients are appropriately managed before CCM, are appropriately selected for CCM and are appropriately managed post-procedure. *(CAG-00469)* Therefore, use of optimized GDMT and patient outcomes **must** be very clearly documented in the medical record.

BACKGROUND

A CCM system consists of an implantable pulse generator, ventricular septal pacing leads, an external charger, and an external programming device. CCM devices deliver periodic, programmed electrical stimulation designed to alleviate symptoms associated with HF in order to improve QoL, restore functional capacity, and improve exercise tolerance. CCM delivers electrical stimuli to the ventricular septum during the absolute refractory period. As such, CCM is non-excitatory, meaning it does not trigger cardiac depolarization. The intent of CCM is not to cause the heart to contract, but rather to increase the strength of the heart's contraction. *(CAG-00469)*

On October 28, 2025, Medicare published a Final Decision Memo to detail coverage criteria for CCM for heart failure (HF), which was later converted to NCD 20.39.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

Examples of CCM devices include, but may not be limited to, the following:

- OPTIMIZER® Smart System (Impulse Dynamics)
- Cardiac Contractility Modulation (CCM) System (Optimizer Dynamic)

BILLING GUIDELINES AND CODING

CODES*		
CPT	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
	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

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

None

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
11/2025	New Medicare Advantage medical policy
3/2026	Interim update; replace decision memo with new NCD
11/2026	Interim update; remove cardiac contractility modulation-defibrillator (CCM-D) systems from scope