Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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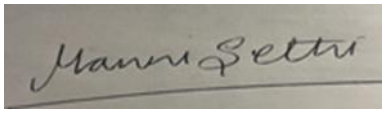
Plan: AmeriHealth Caritas Pennsylvania Community HealthChoices & Keystone First Community HealthChoices	Submission Date: 7/1/2026
Policy Number: CCP.1486	Effective Date: 6/1/2021 Revision Date: 6/1/2026
Policy Name: Cardiac contractility modulation	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Keystone First
Community HealthChoices

Cardiac contractility modulation

Clinical Policy ID: CCP.1486

Recent review date: 6/2026

Next review date: 10/2027

Policy contains: Cardiac contractility modulation; chronic heart failure.

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First Community HealthChoices, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

The Implantable Optimizer® Smart System for delivering Cardiac Contractility ModulationTM (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.
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Background

Heart failure occurs when the heart cannot pump enough blood and oxygen to support other organs. Nearly 6.7 million United States adults age 20 years or older have heart failure. In 2023, heart failure was mentioned on 452,573 death certificates and accounted for 14.6 percent of all causes of death (Centers for Disease Control and Prevention, 2024).

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, or dyspnea (shortness of breath).
- Class II: Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, or 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 fraction have reduced morbidity and mortality. However, only one-third of patients meet criteria for an implantable defibrillator, defined by left ventricular ejection fraction less than or equal to 35 percent, and for cardiac resynchronization therapy, defined by ventricular depolarization duration greater than or equal to 130 milliseconds and evidence of left bundle branch block. Symptoms fail to improve in many patients who meet criteria for cardiac resynchronization therapy (Cappannoli, 2021). The five-year survival rate for patients with heart failure with reduced ejection fraction has remained about 50 percent in the past several decades (Giallauria, 2020).

Cardiac contractility modulation delivers non-excitatory electrical signals during the absolute refractory period to improve myocardial contractility properties without initiating a new depolarization. United States Food and Drug Administration product code QFV defines the device as an implantable pulse generator that delivers cardiac contractility modulation signals during the absolute refractory period, electrically stimulates the heart during that period to improve cardiac contractility properties, is Class Three, and requires premarket approval review (United States Food and Drug Administration, 2026). The Optimizer Smart Mini system is implanted with two right ventricular leads for sensing and cardiac contractility modulation therapy delivery, with an optional atrial lead used for sensing in three-lead mode (Impulse Dynamics, 2022).

On March 21, 2019, the United States Food and Drug Administration granted premarket approval P180036 to Impulse Dynamics for the Optimizer Smart System. The original indication was to improve six-minute hall walk distance, quality of life, and functional status in New York Heart Association Class III heart failure patients who remained symptomatic despite guideline-directed medical therapy, were in normal sinus rhythm, were not indicated for cardiac resynchronization therapy, and had a left ventricular ejection fraction from 25 percent to 45 percent (United States Food and Drug Administration, 2019). The original United States Food and Drug Administration indication was New York Heart Association Class III heart failure and should not be described as Class III or IV.

On October 6, 2021, the United States Food and Drug Administration approved supplement P180036/S008 for the Optimizer Smart System and Optimizer Smart Mini System, removing the indication requirement that patients be in normal sinus rhythm (United States Food and Drug Administration, 2021). Current Optimizer Smart Mini labeling lists contraindications for patients with a mechanical tricuspid valve and for patients in whom vascular access for implantation of the leads cannot be obtained; it does not retain the earlier normal-sinus-rhythm-based atrial fibrillation exclusion in the indication (Impulse Dynamics, 2022).

Subsequent United States Food and Drug Administration premarket approval supplement records identify the Optimizer Smart Mini System and Optimizer Lite system as part of the same Impulse Dynamics cardiac contractility modulation product family under premarket approval P180036. On August 3, 2023, the United States Food and Drug Administration approved supplement P180036/S021 to add the Optimizer Lite system version. On April 10, 2026, the United States Food and Drug Administration approved supplement P180036/S041 for

design changes to the GUARDIO/VESTA Charger power supply connector (United States Food and Drug Administration, 2023; United States Food and Drug Administration, 2026).

Public United States Food and Drug Administration records reviewed through May 16, 2026, including premarket approval, product classification, total product life cycle, recall, supplement, and product code QFV records, support limiting the United States-authorized cardiac contractility modulation product family for chronic heart failure to Impulse Dynamics Optimizer devices under premarket approval P180036. The statement that Optimizer Smart and Optimizer Smart Mini are the only such products is incomplete because United States Food and Drug Administration records also identify Optimizer Lite. Public database searches did not identify a separate non-Impulse Dynamics cardiac contractility modulation product family authorized for chronic heart failure, but absolute exclusivity cannot be established solely from negative public database searches because Food and Drug Administration indexing, registration and listing terminology, and accessory naming can vary (United States Food and Drug Administration, 2026).

In 2024, the United States Food and Drug Administration posted a Class Two recall for Optimizer Smart Mini and Optimizer Lite model X11 implantable pulse generator devices. The recall involved a software issue in which devices may cease to deliver cardiac contractility modulation therapy if the device incorrectly detects a charging error, potentially causing patients to experience heart failure symptoms similar to symptoms before implantation (United States Food and Drug Administration, 2024).

The United States Food and Drug Administration post-approval study for the Optimizer Smart System remains ongoing. The current protocol, accepted April 8, 2025, is a prospective, nonrandomized, multicenter, single-arm open-label cohort intended to provide long-term safety and effectiveness data in patients with New York Heart Association Class III symptoms and reduced or mildly reduced ejection fraction from 25 percent to 45 percent. Interim post-approval data include device-related adverse event rates, observed survival compared with Seattle Heart Failure Model-predicted survival, and changes in quality of life and functional measures; the final report is due June 29, 2029. These data are useful for safety surveillance but do not replace randomized comparative evidence for mortality or heart failure hospitalization outcomes (United States Food and Drug Administration, 2026).

Findings

The 2022 American College of Cardiology, American Heart Association, and Heart Failure Society of America Guideline for the Management of Heart Failure did not provide a formal recommendation for cardiac contractility modulation and identified the safety and efficacy of cardiac contractility modulation in heart failure as an evidence gap and future research direction (American College of Cardiology, American Heart Association, and Heart Failure Society of America, 2022 Guideline for the Management of Heart Failure).

National Institute for Health and Care Excellence HealthTech guidance 520, which migrated and replaced interventional procedures guidance 655 without changing the recommendations or accompanying content, states that cardiac contractility modulation device implantation for heart failure raises no major safety concerns but that evidence on efficacy is inadequate in quantity and quality. The guidance states that the procedure should only be used in the context of research and that further research should ideally be randomized and report patient selection, duration and timing of stimulation, duration of effect, ejection fraction, oxygen consumption, New York Heart Association classification, and patient-reported outcomes including quality of life (National Institute for Health and Care Excellence, Cardiac contractility modulation device implantation for heart failure).

The Heart Failure Association of the European Society of Cardiology Clinical Practice Update on Heart Failure 2019 states that cardiac contractility modulation may be considered in patients with a left ventricular ejection fraction of 25 percent to 45 percent and narrow ventricular depolarization duration less than 130 milliseconds to

improve exercise capacity, quality of life, and heart failure functional status (Heart Failure Association of the European Society of Cardiology, Clinical Practice Update on Heart Failure 2019).

The American College of Cardiology, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance 2025 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators, Cardiac Resynchronization Therapy, and Pacing rated cardiac contractility modulation as May Be Appropriate for selected heart failure patients who are not candidates for cardiac resynchronization therapy and have ventricular depolarization duration less than 130 milliseconds across New York Heart Association Class II and Class III or IV categories. The rating table assigns May Be Appropriate scores for left ventricular ejection fraction less than 25 percent, 25 percent to 35 percent, and 36 percent to 45 percent, although United States Food and Drug Administration approval remains for New York Heart Association Class III patients with left ventricular ejection fraction 25 percent to 45 percent. The appropriate use criteria state that studies have shown improvements in quality of life, New York Heart Association functional class, six-minute walk distance, and peak oxygen consumption, but that studies have not been powered for morbidity or mortality, current practice guidelines do not provide formal cardiac contractility modulation recommendations, and larger studies evaluating longer-term clinical outcomes are needed (American College of Cardiology, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance, 2025 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators, Cardiac Resynchronization Therapy, and Pacing).

A randomized controlled trial of 160 participants that led to United States 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 score (probability value less than .001), New York Heart Association functional class (probability value less than .001), and six-minute hall walk distance (probability value = .02). The composite rate of cardiovascular death and heart failure hospitalizations declined from 10.8 percent to 2.9 percent (probability value = .048) (Abraham, 2018).

A prospective study of cardiac contractility modulation delivered by the two-lead Optimizer Smart System evaluated safety, performance, and efficacy of the simplified device configuration. The study supports the safety and performance rationale for the two-lead system but does not provide definitive evidence of reduced mortality or heart failure hospitalization (Wiegn, 2020).

A review of 475 hospitalized patients with heart failure in the United Kingdom found that 24 patients (5.1 percent) met narrow cardiac contractility modulation eligibility criteria defined by left ventricular ejection fraction 25 percent to 45 percent, ventricular depolarization duration less than 130 milliseconds, New York Heart Association Class III or IV symptoms, and stable treatment for heart failure for more than 90 days. Exclusion criteria included significant valvular disease, permanent or persistent atrial fibrillation, an implanted biventricular pacing system or ventricular depolarization duration greater than 130 milliseconds, and unsuitability for device therapy because of palliative treatment intent. Patients with heart failure and atrial fibrillation represented an additional 3.8 percent under the earlier sinus-rhythm-based criteria, but United States Food and Drug Administration supplement P180036/S008 later removed the normal sinus rhythm requirement from the indication (Dulai, 2021; United States Food and Drug Administration, 2021).

Systematic reviews and meta-analyses consistently report short-term improvements in quality of life, symptoms, exercise capacity, peak oxygen consumption, six-minute walk distance, or New York Heart Association functional class in selected patients receiving cardiac contractility modulation. However, the evidence remains insufficient

to establish durable reductions in all-cause mortality, cardiovascular mortality, arrhythmic events, or heart failure hospitalization. Potential indications have expanded from earlier trial populations with sinus rhythm and narrow ventricular depolarization duration to patients with atrial fibrillation after removal of the normal sinus rhythm requirement, but available evidence remains limited by short follow-up, selected trial populations, heterogeneous study designs, limited power for hard clinical outcomes, and reliance on observational or single-arm data in newer reports.

A systematic review and meta-analysis of four randomized controlled trials with 801 participants 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 (probability value = .0008). The study found no differences between groups in heart failure hospitalizations (probability value = .12), all-cause hospitalizations (probability value = .33), six-minute walk distance (probability value = .10), arrhythmias (probability value = .14), pacemaker and implantable cardioverter-defibrillator malfunctions (probability value = .06), or all-cause mortality (probability value = .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 with 861 participants of cardiac contractility modulation for heart failure revealed superior outcomes after six months for cases versus controls for peak oxygen consumption (probability value less than .00001), six-minute walk test distance (probability value = .005), and Minnesota Living with Heart Failure Questionnaire scores (probability value less than .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 2025 systematic review and single-arm meta-analysis evaluated cardiac contractility modulation in symptomatic heart failure with reduced ejection fraction, with emphasis on functional, structural, and quality-of-life outcomes among patients with narrow ventricular depolarization duration who were ineligible for cardiac resynchronization therapy. The analysis adds contemporary synthesis of post-2020 evidence, but its single-arm design limits causal inference and does not resolve uncertainty about mortality or heart failure hospitalization outcomes (Suruagy-Motta, 2025).

A meta-analysis of four trials with 723 participants 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 (probability value = .006) and the six-minute walk test distance (probability value = .049) (Liu, 2017).

In 2023, we added the American College of Cardiology, American Heart Association, and Heart Failure Society of America 2022 Guideline for the Management of Heart Failure, which identifies cardiac contractility modulation as an evidence gap and does not provide a formal recommendation for or against use (American College of Cardiology, American Heart Association, and Heart Failure Society of America, 2022 Guideline for the Management of Heart Failure).

In 2024, we deleted older references and added the United States Food and Drug Administration Class Two recall for Optimizer Smart Mini and Optimizer Lite model X11 implantable pulse generators. The recall is relevant to safety surveillance and device management but does not establish comparative clinical effectiveness (United States Food and Drug Administration, 2024).

In 2025, we added the American College of Cardiology, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance 2025 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators, Cardiac Resynchronization Therapy, and Pacing, which rates cardiac contractility modulation as May Be

Appropriate for selected patients not eligible for cardiac resynchronization therapy with ventricular depolarization duration less than 130 milliseconds. The same document states that practice guidelines do not provide formal cardiac contractility modulation recommendations and that evidence for hard outcomes such as heart failure hospitalization and mortality remains limited (American College of Cardiology, American Heart Association, American Society of Echocardiography, Heart Failure Society of America, Heart Rhythm Society, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, and Society for Cardiovascular Magnetic Resonance, 2025 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators, Cardiac Resynchronization Therapy, and Pacing).

In 2026, we added Suruagy-Motta, 2025; Wiegn, 2020; and American College of Cardiology, 2025. No policy changes were warranted.

References

On May 16, 2026, we searched PubMed and the databases of the Cochrane Library, the United Kingdom National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, the United States Food and Drug Administration premarket approval, premarket notification, De Novo, Humanitarian Device Exemption, device classification, product code, Registration and Listing, recall, labeling, post-approval study, and total product life cycle databases, and AccessGUDID. Search terms included “cardiac contractility modulation,” “cardiac contractility modulation therapy,” “Optimizer,” “Optimizer Smart,” “Optimizer Smart Mini,” “Optimizer Lite,” “Impulse Dynamics,” “implantable pulse generator,” “non-excitatory electrical stimulation,” “nonexcitatory electrical stimulation,” “P180036,” and “QFV.” We included the best available evidence according to established evidence hierarchies, including systematic reviews, meta-analyses, randomized controlled trials, prospective comparative studies, retrospective comparative studies, registries, post-approval studies, professional society guidelines, appropriate use criteria, consensus statements, scientific statements, and position statements. We excluded United States payer medical policies, prior authorization criteria, reimbursement policies, and coverage determinations as clinical evidence, but considered Centers for Medicare and Medicaid Services National Coverage Determination 20.39 for Medicare coverage and coding requirements.

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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.

6/2026: Policy references updated.

Related codes

Below are the most commonly submitted codes for the services or items subject to this policy CCP.1486. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code description
0408T through 0418T	Insertion, replacement, removal, repositioning, relocation, programming, and in-person interrogation services for permanent cardiac contractility modulation systems.
0948T through 0949T	Remote interrogation device evaluation of a cardiac contractility modulation system, up to 90 days, including the physician or other qualified health care professional component and the technical component.
C1824	Generator, cardiac contractility modulation, implantable.
C1898	Pacemaker lead other than a transvenous single-pass lead used for atrial sensing with ventricular pacing.
K1030	External recharging system for an internal battery, for use with an implanted cardiac contractility modulation generator, replacement only.