Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 9/1/24**
(See policy history boxes for previous effective dates)

Title: Intensive Cardiac Rehabilitation

Description/Background

Heart disease is the leading cause of mortality in the United States, accounting for more than half of all deaths. Coronary artery disease (CAD) is the most common cause of heart disease. In the 2020 update on heart disease and stroke statistics from the American Heart Association, it was estimated that 605,000 Americans have a new coronary attack (first hospitalized myocardial infarction or coronary heart disease death) and 335,000 have a recurrent attack annually.[1] Both CAD and various other disorders - structural heart disease and other genetic, metabolic, endocrine, toxic, inflammatory, and infectious causes – can lead to the clinical syndrome of heart failure.[2] Given the burden of heart disease, preventing secondary cardiac events and treating the symptoms of heart disease and heart failure have received much attention from national organizations.

Cardiac Rehabilitation

In 1995, the U.S. Public Health Service (USPHS) defined cardiac rehabilitation services as, in part, “comprehensive, long-term programs involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling…. [These programs are] designed to limit the physiologic and psychological effects of cardiac illness, reduce the risk for sudden death or reinfarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the psychosocial and vocational status of selected patients.” This USPHS guideline recommended cardiac rehabilitation services for patients with coronary heart disease and heart failure, including those awaiting or following cardiac transplantation. A 2010 definition of cardiac rehabilitation from the European Association of Cardiovascular Prevention and Rehabilitation stated: “Cardiac rehabilitation can be viewed as the clinical application of preventive care by means of a professional multi-disciplinary integrated approach for comprehensive risk reduction and global long-term care of cardiac patients.”[3] Since release of the USPHS guideline, other societies, including the American Heart

Association (2005)[4] and the Heart Failure Society of America (2010)[5] have developed guidelines on the role of cardiac rehabilitation in patient care.

Cardiac rehabilitation refers to comprehensive medically supervised programs in the outpatient setting that aim to improve the function of patients with heart disease and prevent future cardiac events. National organizations have specified core components of cardiac rehabilitation programs, which include:

- physician-prescribed exercise each day cardiac rehabilitation services are provided;
- cardiac risk factor modification;
- psychosocial assessment;
- outcomes assessment; and
- individualized treatment plan detailing how each of the above components are utilized.

Intensive cardiac rehabilitation (ICR)

Intensive cardiac rehabilitation (ICR) represents a more comprehensive and non-pharmacological approach to CR, placing significant emphasis on non-exercise activities. ICR focuses on lifestyle modifications, with preference for adopting a low-fat, plant-based diet, which can be a favorable influence on secondary prevention of cardiovascular diseases. ICR includes dietary modifications, dedicated peer support, and stress management, all in addition to exercise. ICR has demonstrated its advantages for patients dealing with a wide range of cardiovascular disease.

There are three examples of the ICR programs (Ornish, Pritikin, and Benson) available for eligible patients. The Dean Ornish Cardiac Rehabilitation Program is structured around a strict, plant-based diet that and emphasizes fruits, legumes, vegetables, whole grains, and non-fat dairy which is all low in fat. Its primary goal is to reduce cholesterol levels and promote heart health through healthier dietary choices. The program includes a fitness regimen that encompasses both aerobic and strength training exercises to enhance cardiovascular fitness. Stress reduction is a central concentration, involving practices such as meditation and relaxation techniques. Additionally, participants are often encouraged to engage in group support to facilitate the adoption and healthy lifestyle changes. The Pritikin Program, similar to Dean Ornish's approach, places a strong emphasis on a plant-based, low-fat diet, with a particular focus on whole, unprocessed foods and the reduction of added sugars. It advocates regular physical activity to enhance overall fitness and cardiovascular well-being. In addition, this program prioritizes education by empowering participants with the information needed to make informed decisions about their nutrition, fitness, and overall health. Additionally, it frequently includes strategies for managing weight effectively, enabling individuals to achieve and maintain a healthy weight. Benson's program is well known for its focus on mind–body approaches, notably the relaxation response, aimed at stress reduction and fostering relaxation. It promotes the adoption of a healthier lifestyle, encompassing dietary improvements, regular physical activity, and effective stress management. Key to the program are practices like meditation and relaxation exercises, which play a pivotal role in stress management and overall well-being enhancement.

Additionally, the programs may adopt a more personalized approach, tailoring interventions to the unique requirements and preferences of each participant. Although all three above mentioned ICR programs have received approval for payment from federal payers, their utilization remains low in the broader population.

Medicare, on their *Cardiac rehabilitation* page, states that Medicare Part B covers comprehensive cardiac rehabilitation (CR) programs that include exercise, education, and counseling. Part B also covers intensive cardiac rehabilitation (ICR) programs that, like regular CR programs, include exercise, education, and counseling. ICR programs are typically more rigorous or more intense than CR programs. These programs may be provided in a hospital outpatient setting (including a critical access hospital) or in a doctor's office.[7]

ICR programs must be approved by CMS through the NCD process and must meet criteria for approval. In 2010, Medicare-approved intensive cardiac rehabilitation programs included Dr. Ornish's Program for Reversing Heart Disease and the Pritikin Program. Medicare additionally approved the Benson-Henry Institute Cardiac Wellness Program, effective 05/06/2014.

Regulatory Status

N/A

Medical Policy Statement

Intensive Cardiac Rehabilitation (ICR) is experimental/investigational. There is insufficient evidence in the medical literature that ICR improves clinical outcomes over standard cardiac rehabilitation programs.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

G0422* G0423*

*Covered for Medicare

Note: If a member is participating in an intensive cardiac rehabilitation program, services are to be billed with the appropriate G codes. Standard cardiac rehabilitation billing codes should not be used for intensive cardiac rehabilitation services.

Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Although many randomized controlled trials (RCTs) have been published comparing cardiac rehabilitation with usual care for patients, there are no RCTs that compare intensive cardiac rehabilitation to standard cardiac rehabilitation health outcomes. An additional challenge is that there is no standard definition for an intensive cardiac rehabilitation program.

ORNISH PROGRAM FOR REVERSING HEART DISEASE

Clinical Context and Therapy Purpose
The purpose of the Ornish Program for Reversing Heart Disease in patients who have been diagnosed with heart disease is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of the Ornish Program for Reversing Heart Disease in patients who have heart disease improve net health outcomes?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with diagnosed heart disease.

Interventions
The treatment being considered is the Ornish Program for Reversing Heart Disease.

The Ornish Program for Reversing Heart Disease is an intensive cardiac rehabilitation program that focuses on exercise, diet, stress management, and support from others.

The multiple 4-hour sessions are administered by an Ornish-certified physician, cardiac therapist, or other certified health care provider.

Comparators

The comparator of interest is standard outpatient cardiac rehabilitation. Cardiac rehabilitation includes long-term programs that include medical evaluation, prescribed exercise, modification to reduce cardiac risks, education, and counseling.

Outcomes

The general outcomes of interest are overall survival (OS), disease-specific survival, symptoms, and morbid events.

Once diagnosed with heart disease, a patient will require lifelong monitoring by a cardiologist.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

Ornish et al (1990) conducted an RCT, called the Lifestyle Heart Trial, comparing a version of the Ornish Program for Reversing Heart Disease with usual care. Initial results were reported in 1990 and 5-year results in 1998.[8,9] Eligibility for the trial included diagnosed coronary artery disease, left ventricular ejection fraction greater than 25%, no MI during the previous 6 weeks, not scheduled for CABG, and not taking lipid-lowering medication. Ninety-four eligible patients were randomized to an intervention group (n=53) or to a usual care control group (n=43). Final consenting was done after randomization; 28 (53%) of patients assigned to the intervention group and 20 (43%) assigned to the control group agreed to participate in the trial.

The lifestyle intervention consisted of recommending a low-fat vegetarian diet and an individualized exercise regimen. Patients were taught stress management techniques and were taught to practice them at home for at least an hour a day. Also, twice-weekly group discussions were offered to provide social support. It is not clear how long patients attended these group discussions (ie, the number of weeks or months). As reported by Ornish et al (1990), the mean percentage diameter stenosis decreased from 40% at baseline to 37.8% at 1 year in the intervention group and increased from 42.7% to 46.1% in the control group (p=.001). The frequency and duration of chest pain did not differ between groups. However, during chest pain episodes, at 1 year, the intervention group reported mean chest pain severity of 1.7 (on a 7-point scale) whereas the mean score in the control group was 2.5 (p<.001).

Twenty (71%) of 28 patients in the intervention group and 15 (75%) of 20 in the control group complete 5-year follow-up. The intervention and control groups did not differ significantly in the

number of MI events (2 versus 4), CABGs (2 versus 5), or deaths (2 versus 1). However, the intervention group compared with the control group, had significantly fewer percutaneous transluminal coronary angioplasties (8 versus 14, p<.050) and cardiac hospitalizations (23 versus 44, p<.001).

Summary: Ornish Program for Reversing Heart Disease
One RCT was identified that evaluated the Ornish Program in patients diagnosed with heart disease and compared it with usual care. This RCT, which included patients with coronary artery disease but no recent cardiac event, had mixed findings at 1 and 5 years. The trial had a small sample size for a cardiac trial (N=48), and only 35 patients were available for the 5-year follow-up. The Ornish Program is considered by the Centers for Medicare & Medicaid Services to be an intensive cardiac rehabilitation program, but the program described in this RCT might meet the criteria for standard cardiac rehabilitation. No studies were identified that compared the Ornish Program with any other cardiac rehabilitation program.

PRITIKIN PROGRAM

Clinical Context and Therapy Purpose
The purpose of the Pritikin Program in patients who have been diagnosed with heart disease is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with diagnosed heart disease.

Interventions
The treatment being considered is the Pritikin Program.

The Pritikin Program is an intensive cardiac rehabilitation program based on effective exercise, a healthy diet, and a healthy mindset.

Comparators
The comparator of interest is standard outpatient cardiac rehabilitation. Cardiac rehabilitation includes long-term programs that include medical evaluation, prescribed exercise, modification to reduce cardiac risks, education, and counseling.

Outcomes
The general outcomes of interest are OS, disease-specific survival, symptoms, and morbid events.

Once diagnosed with heart disease, a patient will require lifelong monitoring by a cardiologist.

Study Selection Criteria
Study selection criteria is outlined in the first indication.

Nonrandomized Studies

No RCTs evaluating the Pritikin Program were identified. Lakhani et al (2023) conducted a prospective, nonrandomized study that compared intensive cardiac rehabilitation with the Pritikin Program and traditional outpatient cardiac rehabilitation.[18] The primary outcomes of interest were change in diet quality and quality of life from baseline to visit 24. There was a significant improvement in diet quality but not in quality of life between the Pritikin Program and traditional cardiac rehabilitation groups. Body mass index was also improved in patients who received intensive rehabilitation. Limitations of the study include a short follow-up and lack of data for cardiovascular outcomes.

Racette et al (2023) published 7-year outcomes from the first institution to implement the Pritikin Program.[19] Retrospective data for 1507 patients who received the intensive cardiac rehabilitation program and 456 patients who received traditional cardiac rehabilitation were compared. Outcomes of interest (eg, anthropometric measures, dietary patterns, 6-minute walk distance (6MWD), grip strength, and HRQoL) all improved with the Pritiken Program. Significant benefit of the Pritiken Program compared to traditional cardiac rehabilitation were noted for change in body weight (p<.0001), body mass index (p<.0001), waist circumference (p<.0001), and diet quality as measured by the Rate Your Plate score (p<.0001). There was no difference in 6MWD or grip strength between groups. Cardiovascular outcomes, including rehospitalization or mortality, were not assessed.

Table 1. Summary of Key Nonrandomized Trials

Study	Study Type	Country	Dates	Participants	Intensive Cardiac Rehab	Traditional Cardiac Rehab	Follow-Up
Lakhani et al (2023)[18]	Cohort	U.S.	2017-2021	Referred by a cardiologist for cardiac rehabilitation	n=230	N=62	24 visits
Racette et al (2022) [19]	Cohort	U.S.	2013-2019	Enrolled in a cardiac rehabilitation program in the course of usual care	N=1507	N=456	72 sessions over 18 weeks; 7 year follow-up

Table 1. Summary of Key Nonrandomized Trials

Study	Change in diet quality	Change in QOL	Change in body weight (kg)	Change in BMI (kg/m$^{2)}$	Change in 6MWD (m)
Lakhani et al (2023) [18]	N=292	N=292	NR	NR	NR
Intensive cardiac rehabilitation	• 90% improved • 3% no change • 7% worsened	• 80% improved • 7% no change • 13% worsened	NR	NR	NR
Traditional cardiac rehabilitation	• 71% improved • 5% no change • 24% worsened	• 71% improved • 13% no change • 16% worsened	NR	NR	NR
p-value	.001	NS	NR	NR	NR
Racette et al (2022) [19]	NR	NR	N=1963	N=1963	N=1963
Intensive cardiac rehabilitation	NR	NR	−1.4±2.8	−0.5±1.0	46.4±57.8
Traditional cardiac rehabilitation	NR	NR	0.1±3.2	0.1±1.1	44.4±58.9
p-value	NR	NR	<.001	<.001	106

6MWD: 6-minute walk distance; BMI: body mass index; NS: not significant; QOL: quality of life.

Review of Evidence

Case Series

Section Summary: Pritikin Program

No RCTs have evaluated the Pritikin program; 2 nonrandomized studies in patients with heart disease were identified. Conclusions cannot be drawn from this limited data on the impact on cardiovascular outcomes of intensive cardiac rehabilitation with the Pritikin program compared with standard outpatient cardiac rehabilitation.

BENSON-HENRY INSTITUTE CARDIAC WELLNESS PROGRAM

Clinical Context and Therapy Purpose

The purpose of the Benson-Henry Institute Program in individuals who have been diagnosed with heart disease is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with diagnosed heart disease.

Interventions
The treatment being considered is the Benson-Henry Institute Program.

The Benson-Henry Institute Program is an intensive cardiac rehabilitation program based on effective exercise, a healthy diet, and a healthy mindset.

Comparators
The comparator of interest is standard outpatient cardiac rehabilitation. Cardiac rehabilitation includes long-term programs that include medical evaluation, prescribed exercise, modification to reduce cardiac risks, education, and counseling.

Outcomes
The general outcomes of interest are OS, disease-specific survival, symptoms, and morbid events.

Once diagnosed with heart disease, a patient will require lifelong monitoring by a cardiologist.

Study Selection Criteria
Study selection criteria is outlined in the first indication.

Review of Evidence

Case-Control Studies
Zeng et al (2013) reported outcomes of a Medicare-sponsored demonstration of 2 intensive lifestyle modification programs in patients with symptomatic coronary heart disease: the Cardiac Wellness Program of the Benson-Henry Mind Body Institute and the Dr. Dean Ornish Program for Reversing Heart Disease.[11] This analysis included 461 participants and 1795 matched controls using Medicare claims data from 1998 to 2008. Four matched controls were sought for each participant from Medicare claims data, 2 of whom had received traditional cardiac rehabilitation within 12 months following their cardiac events (cardiac rehabilitation controls) and 2 of whom had not (non-cardiac rehabilitation controls). Outcomes included mortality rates during the 3 post-enrollment years, total hospitalizations, hospitalizations with a cardiac-related principal discharge diagnosis, and Medicare-paid costs of care. Of the 324 participants in the Benson-Henry Mind Body Medical Institute program analysis, the authors concluded that during the active intervention and follow-up years, total, cardiac, and non-cardiac hospitalizations were lower in the Benson-Henry program participants than their controls for each comparison ($p<.001$). The investigators further reported that after year 1, the mortality rate was 1.5% in the Benson-Henry program participants compared with 2.5% and 4.2%, respectively, in cardiac rehabilitation and noncardiac rehabilitation controls. After year 3, comparable figures were 6.2% in Benson-Henry program participants, 10.5% in cardiac rehabilitation controls, and 11.0% in non-cardiac rehabilitation controls. These mortality differences for the Benson-Henry program participants reached borderline significance ($p=.08$).

Case Series
Casey et al (2009) reported the results of a case series that evaluated the effects of an intensive cardiac rehabilitation program, incorporating components of the Benson-Henry Institute Cardiac Wellness Program at a single center.[12] From 1997 to 2005, 637 patients with coronary artery disease were enrolled and completed the program, which consisted of 13 weekly 3 hour sessions with supervised exercise, relaxation techniques, stress management, and behavioral interventions. The mean age of participants was 63 years (range 27 to 92 years); men comprised 72% of the study population. Results revealed significant improvements in clinical (blood pressure, lipids, weight, exercise conditioning, frequency of symptoms of chest pain, and shortness of breath) and psychological outcomes (general severity index, depression, anxiety, and hostility) ($p<.0001$) with the program.

Section Summary: Benson-Henry Institute Program
No RCTs have evaluated the Benson-Henry Institute Program; a case-control study found the program participants to have lower total, cardiac, and non-cardiac hospitalizations during the active intervention and follow-up years compared to controls for each comparison. Additionally, program participants had lower mortality rates compared to controls; however, the mortality differences were borderline significant at year 3. A case series also demonstrated that the implementation of components of the Benson-Henry Institute program resulted in an improvement in clinical and psychological outcomes. Conclusions cannot be drawn from these data on the impact of intensive cardiac rehabilitation with the Benson Henry Institute program compared with standard outpatient cardiac rehabilitation.

Summary of Evidence
For individuals who have been diagnosed with heart disease and who receive intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease, the evidence includes multiple randomized controlled trials (RCTs) and uncontrolled studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, and morbid events. No RCTs have compared the Ornish Program with a “standard” cardiac rehabilitation program; an RCT compared it with usual care. The trial included patients with coronary artery disease and no recent cardiac events and had mixed findings at 1 and 5 years. The trial had a small sample size for a cardiac trial (N=48), and only 35 patients were available for the 5-year follow-up. The Ornish Program is considered by the Centers for Medicare & Medicaid Services as an intensive cardiac rehabilitation program, but the program described in the RCT could meet criteria for standard cardiac rehabilitation. No studies were identified comparing the Ornish Program with any other cardiac rehabilitation program. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have been diagnosed with heart disease and who receive intensive cardiac rehabilitation with the Pritikin Program, the evidence includes 2 nonrandomized studies . Relevant outcomes are OS, disease-specific survival, symptoms, and morbid events. Studies are needed that compare the impact of intensive cardiac rehabilitation using the Pritikin Program with standard outpatient cardiac rehabilitation programs for these outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have been diagnosed with heart disease and who receive intensive cardiac rehabilitation with the Benson-Henry Institute Program, the evidence includes a case-control study and case series. Relevant outcomes are OS, disease-specific survival,

symptoms, and morbid events. Studies are needed that compare the impact of intensive cardiac rehabilitation using the Benson-Henry Institute Program with standard outpatient cardiac rehabilitation programs. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

There are no practice guidelines or position statements found that are specific to Intensive Cardiac Rehabilitation.

American College of Cardiology Foundation/American Heart Association

The 2022 American College of Cardiology (ACC) and the American Heart Association (AHA) heart failure guidelines recommend rehabilitation for Stage C heart failure stating, "In patients with HF, a cardiac rehabilitation program can be useful to improve functional capacity, exercise tolerance, and health-related QOL." [25]

In 2023, the ACC/AHA published a statement on supervised exercise training specific to patients with chronic heart failure with preserved ejection fraction (HFpEF) and concluded, "data reviewed herein demonstrate a comparable or larger magnitude of improvement in exercise capacity from supervised exercise training in patients with chronic HFpEF compared with those with heart failure with reduced ejection fraction." [26]

American Heart Association

In 2007, the American Heart Association and the American Association of Cardiovascular and Pulmonary Rehabilitation issued a consensus statement on the core components of cardiac rehabilitation programs.[2,] The core components included patient assessment before beginning the program, nutritional counseling, weight management, blood pressure management, lipid management, diabetes management, tobacco cessation, psychosocial management, physical activity counseling, and exercise training. Programs that only offered supervised exercise training were not considered cardiac rehabilitation. The guidelines specified the assessment, interventions, and expected outcomes for each of the core components. For example, symptom-limited exercise testing before exercise training was strongly recommended. The guidelines did not specify the optimal overall length of programs or the number or duration of sessions.

In 2019, the American Heart Association, with the American Association of Cardiovascular and Pulmonary Rehabilitation and the American College of Cardiology, released a scientific statement on home-based cardiac rehabilitation (HBCR).[27] They make the following suggestions for healthcare providers:

- Recommend center-based cardiac rehabilitation (CBCR) to all eligible patients.
- As an alternative, recommend home-based cardiac rehabilitation (HBCR) to clinically stable low- and moderate-risk patients who cannot attend CBCR.
- Design and test HBCR "using effective processes of care for CVD [cardiovascular disease] secondary prevention."
- For healthcare organizations, develop and support the following:
    - Maximization of cardiac rehabilitation (CR) referrals
    - High-quality CBCR and HBCR programs "using evidence-based standards and guidelines, strategies to maximize patient adherence both in the shorter and longer-term, and outcome tracking methods to help promote continuous quality improvement."
    - "Testing and implementation of an evidence-based hybrid approach to CR" that are optimized for each patient and that "promote long-term adherence and favorable behavior change."
- For CR professionals, "work with other healthcare professionals and policymakers to implement additional research and...expand the evidence base for HBCR."

Medicare National Coverage
Cardiac Rehabilitation

Since 1989, Medicare has had a national coverage determination (NCD) for cardiac rehabilitation. The NCD was retired in April 2023. CMS periodically retires NCDs that no longer contain clinically pertinent and/or current information or no longer reflect current medical practice. In the absence of NCDs, coverage determinations are made by the Medicare Administrative Contractors (MACs) under section 1862(a)(1)(A) of the Social Security Act.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT. No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06077201	Home-Based Cardiac Rehabilitation Using a Novel Mobile Health Exercise Regimen Following Transcatheter Heart Valve Interventions	375	Oct 2026
NCT05933083	MCNAIR Study: coMparative effeCtiveness of iN-person and teleheAlth cardIac Rehabilitation	516	Oct 2027
NCT05972070	Integration of Telemedicine and Home-Based Cardiac Rehabilitation: Feasibility, Efficacy, and Adherence	500	Nov 2023
NCT04245813	Effectiveness of a Cardiac Rehabilitation Program in Patients With Heart Failure	144	May 2023
NCT02984449	Preventive Heart Rehabilitation in Patients Undergoing Elective Open Heart Surgery to Prevent Complications and to Improve	350	Aug 2025

	Quality of Life (Heart-ROCQ) - A Prospective Randomized Open Controlled Trial, Blinded End-point (PROBE)		
NCT05270993	An Integrative Cardiac Rehabilitation Employing Smartphone Technology (iCREST) for Patients With Post-myocardial Infarction: A Randomized Controlled Trial	124	Dec 2023
NCT05689385	The Effectiveness of eHealth-based Cardiac Rehabilitation in Post-myocardial Infarction Patients：a Randomized Controlled Trial	150	Dec 2024
NCT05610358	Efficacy of Smartphone Application Based Rehabilitations in Patients With Chronic Respiratory or Cardiovascular Disease	162	Dec 2024
NCT02791685	Smartphone Delivered In-home Cardiopulmonary Rehabilitation	300	Dec 2026

NCT: national clinical trial.

Government Regulations
National:

National Coverage Determination (NCD) for Intensive Cardiac Rehabilitation (ICR) Programs (20.31)
Effective Date: 08/12/2010
Implementation Date: 10/25/2010

Intensive cardiac rehabilitation (ICR) refers to a physician-supervised program that furnishes cardiac rehabilitation services more frequently and often in a more rigorous manner. As required by §1861(eee)(4)(A) of the Social Security Act (the Act), an ICR program must show, in peer-reviewed published research, that it accomplished one or more of the following for its patients: (1) positively affected the progression of coronary heart disease; (2) reduced the need for coronary bypass surgery; and, (3) reduced the need for percutaneous coronary interventions. The ICR program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in five or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services: (1) low density lipoprotein; (2) triglycerides; (3) body mass index; (4) systolic blood pressure; (5) diastolic blood pressure; and, (6) the need for cholesterol, blood pressure, and diabetes medications. Individual ICR programs must be approved through the national coverage determination process to ensure that they demonstrate these accomplishments.

National Coverage Determination (NCD) for The Pritikin Program (20.31.1)
Effective Date: 08/12/2010
Implementation Date: 10/25/2010

A. General

The Pritikin diet was designed and adopted by Nathan Pritikin in 1955. The diet was modeled after the diet of the Tarahumara Indians in Mexico, which consisted of 10% fat, 13% protein, 75-80% carbohydrates and provided 15-20 grams per day of crude fiber with only 75 mg/day of cholesterol. Over the years, the Pritikin Program (also known as the Pritikin Longevity Program) evolved into a comprehensive program that is provided in a physician’s office and incorporates a specific diet (10%-15% of calories from fat, 15%-20% from protein, 65%-75% from complex carbohydrates), exercise, and counseling lasting 21-26 days. An optional residential component is also available for participants.

B. Nationally Covered Indications

Effective for claims with dates of service on and after August 12, 2010, the Pritikin Program meets the intensive cardiac rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act and in regulations at 42 C.F.R. §410.49(c) and, as such, has been included on the list of approved ICR programs available at http://www.cms.gov/MedicareApprovedFacilitie/.

National Coverage Determination (NCD) for Ornish Program for Reversing Heart Disease (20.31.2)
Effective Date: 08/12/2010
Implementation Date: 10/25/2010

A. General

The Ornish Program for Reversing Heart Disease (also known as the Multisite Cardiac Lifestyle Intervention Program, the Multicenter Cardiac Lifestyle Intervention Program, and the Lifestyle Heart Trial Program) was initially described in the 1970s and incorporates comprehensive lifestyle modifications including exercise, a low-fat diet, smoking cessation, stress management training, and group support sessions. Over the years, the Ornish Program has been refined but continues to focus on these specific risk factors.

B. Nationally Covered Indications

Effective for claims with dates of service on and after August 12, 2010, the Ornish Program for Reversing Heart Disease meets the Intensive Cardiac Rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act, and in regulations at 42 C.F.R. §410.49(c) and, as such, has been included on the list of approved ICR programs available at http://www.cms.gov/MedicareApprovedFacilitie/.

National Coverage Determination (NCD) for Benson-Henry Institute Cardiac Wellness Program (20.31.3)
Effective Date 05/06/2014
Implementation Date 11/04/2014

A. General

The fundamental concepts of the Benson-Henry Institute Cardiac Wellness Program were developed by Herbert Benson, MD, over 40 years ago. Benson states that “in the middle 1960s, when I noticed that people’s blood pressures were higher during visits to my office than at other times and wondered whether stress wasn’t causing that rise. Stress wasn’t on the radar then, so I began investigating a connection between stress and hypertension.” (http://www.ideafit.com/fitness-library/mind-body-medicine-balanced-approach) The Cardiac Wellness Program is a multi-component intervention program that includes supervised exercise, behavioral interventions, and counseling, and is designed to reduce cardiovascular risk and improve health outcomes.

B. Nationally Covered Indications

Effective for claims with dates of service on and after May 6, 2014, the Benson-Henry Institute Cardiac Wellness Program meets the Intensive Cardiac Rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act, and in regulations at 42 C.F.R. §410.49(c) and, as such, has been included on the list of approved ICR programs available at http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/ .

C. Nationally Non-Covered Indications
Effective May 6, 2014, if a specific ICR program is not included on the above-noted list as a Medicare-approved ICR program, it is non-covered.

Medicare Benefit Policy Manual, Chapter 15, Section 232 Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished on or after January 1, 2024
(Rev. 12497; Issued: 02-08-24; Effective: 01-01-24; Implementation: 03-12-24

Cardiac rehabilitation (CR) means a physician or nonphysician practitioner supervised program that furnishes physician prescribed exercise; cardiac risk factor modification, including education, counseling, and behavioral intervention; psychosocial assessment; and outcomes assessment. Intensive cardiac rehabilitation (ICR) program means a physician or nonphysician practitioner supervised program that furnishes CR and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in 42 CFR 410.49(c). Nonphysician practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as those terms are defined in section 1861(aa)(5)(A) of the Social Security Act (the Act).
Effective January 1, 2010, Medicare Part B pays for CR/ICR if specific criteria are met by the Medicare beneficiary, the CR/ICR program itself, the setting in which it is administered, and the physician administering the program, as outlined below.

Covered Conditions:

As specified in 42 CFR 410.49, Medicare Part B covers CR and ICR for beneficiaries who have experienced one or more of the following:
• An acute myocardial infarction (MI) within the preceding 12 months;
• A coronary artery bypass surgery;
• Current stable angina pectoris;
• Heart valve repair or replacement;
• Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting;
• A heart or heart-lung transplant.
• Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, on or after February 18, 2014, for CR and on or after February 9, 2018, for ICR; or
• Other cardiac conditions as specified through a national coverage determination (NCD). The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

CR and ICR must include all of the following components:

Physician-prescribed exercise. Physician-prescribed exercise means aerobic exercise combined with other types of exercise (such as strengthening and stretching) as determined to be appropriate for individual patients by a physician each day CR/ICR items and services are furnished.

Cardiac risk factor modification. Cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to the individual's needs. Psychosocial assessment. Psychosocial assessment means an evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation which includes an assessment of those aspects of an individual's family and home situation that affects the individual's rehabilitation treatment, and psychosocial evaluation of the individual's response to and rate of progress under the treatment plan. Outcomes assessment. Outcomes assessment means an evaluation of progress as it relates to the individual's rehabilitation which includes all of the following: (i) Evaluations, based on patient-centered outcomes, which must be measured by the physician or program staff at the beginning and end of the program. Evaluations measured by program staff must be considered by the physician in developing and/or reviewing individualized treatment plans. (ii) Objective clinical measures of exercise performance and self-reported measures of exertion and behavior.

Individualized treatment plan. Individualized treatment plan means a written plan tailored to each individual patient that includes all of the following: (i) A description of the individual's diagnosis. (ii) The type, amount, frequency, and duration of the items and services furnished under the plan. (iii) The goals set for the individual under the plan. The individualized treatment plan detailing how components are utilized for each patient, must be established, reviewed, and signed by a physician every 30 days. As specified at 42 CFR 410.49(f)(1), the number of CR sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare Administrative Contractor (MAC).

As specified at 42 CFR 410.49(f)(2), ICR sessions are limited to 72 1-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks.

CR and ICR Settings: Medicare Part B pays for CR and ICR in a physician's office or a hospital outpatient setting. All settings must have a physician or nonphysician practitioner immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician or nonphysician practitioner meets the requirements for direct supervision for physician office services, at 42 CFR 410.26, and for hospital outpatient services at 42 CFR 410.27.

Standards for an ICR Program: To be approved as an ICR program, a program must demonstrate through peer-reviewed, published research that it has accomplished one or more of the following for its patients: (i) Positively affected the progression of coronary heart disease. (ii) Reduced the need for coronary bypass surgery. (iii) Reduced the need for percutaneous coronary interventions. An ICR program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in 5 or more of the following measures for patients from their levels before CR services to after CR services: (i) Low density lipoprotein. (ii) Triglycerides. (iii) Body mass index. (iv) Systolic blood pressure. (v) Diastolic blood pressure. (vi) The need for cholesterol, blood pressure, and diabetes medications. A list of approved ICR programs, identified through the NCD process, will be listed in the Federal Register and is available on the CMS website at https://www.cms.gov/Medicare/Medicare

Local:

There are no LCDs found for Intensive Cardiac Rehabilitation

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Cardiac Rehabilitation, Outpatient

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/9/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/18	12/12/17	12/12/17	Joint policy established
3/1/19	12/11/18		Routine maintenance
3/1/20	12/17/19		Routine maintenance Updated Medicare information – expanded indications for ICR
3/1/21	12/15/20		Routine maintenance
9/1/21	6/15/21		Routine maintenance
9/1/22	6/21/22		Routine maintenance
9/1/23	6/13/23		Routine maintenance (jf) Vendor Managed: NA Ref added, 21-51
9/1/24	6/11/24		Routine maintenance (jf) Vendor Managed: NA • Removal of Virtual Rehab PICO from policy. • Addition of Intensive Cardiac Rehabilitation (ICR) in description section Added Ref: 6,24,25

Next Review Date: 2nd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: INTENSIVE CARDIAC REHABILITATION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.