



Louisiana

Cardiac Rehabilitation in the Outpatient Setting

Policy # 00570

Original Effective Date: 09/20/2017

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider outpatient cardiac rehabilitation programs for individuals with a history of the following conditions and procedures to be **eligible for coverage****:

- Acute myocardial infarction (heart attack) within the preceding 12 months;
- Coronary artery bypass graft surgery;
- Percutaneous transluminal coronary angioplasty or coronary stenting;
- Heart valve surgery;
- Heart or heart-lung transplantation;
- Current stable angina pectoris; or
- Compensated heart failure.

The following components must be included in cardiac rehabilitation programs:

- 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.

A cardiac rehabilitation exercise program is eligible for coverage for 3 sessions per week up to a 12-week period (36 sessions). Programs should start within 90 days of the cardiac event (with exception

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of acute myocardial infarction as noted above) and be completed within 6 months of the cardiac event.

A comprehensive evaluation may be performed before initiation of cardiac rehabilitation to evaluate the individual and determine an appropriate exercise program. In addition to a medical examination, an electrocardiogram stress test may be performed. An additional stress test may be performed at the completion of the program.

Physical and/or occupational therapy are not medically necessary in conjunction with cardiac rehabilitation unless performed for an unrelated diagnosis.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers cardiac rehabilitation in the outpatient setting when criteria are not met to be **investigational**.*

Based on review of available data, the Company considers repeat participation in an outpatient cardiac rehabilitation program in the absence of another qualifying cardiac event to be **investigational**.*

Based on review of available data, the Company considers intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease, Pritikin Program, or Benson-Henry Institute Program to be **investigational**.*

Based on review of available data, the Company considers virtual cardiac rehabilitation to be **investigational**.*

Based on review of available data, the Company considers outpatient cardiac rehabilitation for all other indications (e.g., SARS-CoV-2) to be **investigational**.*

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Background/Overview

Heart disease is the leading cause of mortality in the United States, accounting for more than half of all deaths. Coronary artery disease is the most common cause of heart disease. In a 2024 update on heart disease and stroke statistics from the American Heart Association, it was estimated that 720,000 Americans have a new coronary attack (first hospitalized myocardial infarction or coronary heart disease death) and 335,000 have a recurrent attack annually. Both coronary artery disease 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, of which there are about 650,000 new cases in the United States annually. 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 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.” The U.S. Public Health Service 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.” Since the 1995 release of the U.S. Public Health Service guidelines, other societies, including in 2005 the American Heart Association and in 2010 the Heart Failure Society of America have developed guidelines on the role of cardiac rehabilitation in patient care.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Not applicable.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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 to be included in cardiac rehabilitation programs.

Summary of Evidence

For individuals who have been diagnosed with heart disease and receive outpatient cardiac rehabilitation, the evidence includes multiple randomized controlled trials (RCTs) and systematic reviews of these trials. Relevant outcomes are overall survival (OS), disease-specific survival, symptoms, and morbid events. Meta-analyses of the available trials have found that cardiac rehabilitation improves health outcomes for select patients, particularly those with coronary heart disease, heart failure, and who have had cardiac surgical interventions. The available evidence has limitations, including lack of blinded outcome assessment, but for the survival-related outcomes of interest, this limitation is less critical. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have been diagnosed with heart disease without a second event and receive repeat outpatient cardiac rehabilitation, the evidence includes no trials. Relevant outcomes are OS, disease-specific survival, symptoms, and morbid events. No studies were identified evaluating the effectiveness of repeat participation in a 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 receive intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease, the evidence includes a RCT. Relevant outcomes are OS, disease-specific survival, symptoms, and morbid events. No RCTs have compared the Ornish Program with a “standard” cardiac rehabilitation program; an RCT compared

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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 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 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.

For individuals who have heart disease due to post-acute sequelae of SARS-CoV-2 infection who receive cardiac rehabilitation in the outpatient setting, no relevant evidence was identified. Relevant outcomes are OS, disease-specific survival, symptoms, and morbid events. Limited reports examining the outcomes of rehabilitation in patients with post-acute COVID-19 have not primarily focused on cardiac rehabilitation. 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 receive virtual cardiac rehabilitation, the evidence includes systematic reviews/meta-analyses, RCTs, and observational studies. Relevant outcomes are OS, disease-specific survival, symptoms, and morbid events. Meta-analyses have found beneficial effects of virtual cardiac rehabilitation on physical activity and

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quality of life, but not on cardiovascular hospitalization or mortality. The few available prospective randomized studies have conflicting findings on the effect of virtual cardiac rehabilitation compared to traditional outpatient cardiac rehabilitation for hospital readmission. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

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.

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." 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."

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. 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

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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). They make the following suggestions for healthcare providers:

- Recommend center-based cardiac rehabilitation (CBCR) to all eligible patients.
- As an alternative, recommend 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.”

The guideline does not use the terminology "virtual" cardiac rehabilitation, but it states that electronic tools such as text messaging, smartphone applications, and wearable sensors may allow patients to follow personalized recommendations for exercise, dietary, and behavioral interventions, and thus expand the number of patients who can participate in cardiac rehabilitation. Other benefits of technology-assisted HBCR include greater patient engagement and patient-provider communication. The panel stated that studies were needed regarding the effect of technology-assisted HBCR on outcomes.

U.S. Preventive Services Task Force Recommendations

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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.

In October 2020, virtual cardiac rehabilitation and intensive cardiac rehabilitation were added to the list of telehealth services that Medicare would cover during the COVID-19 public health emergency. Virtual cardiac rehabilitation will continue to be covered through the end of 2024.

Intensive Cardiac Rehabilitation

In January 2010, Medicare added intensive cardiac rehabilitation as a benefit. Intensive cardiac rehabilitation programs must be approved by Medicare on an individual basis.

The national coverage determination described intensive cardiac rehabilitation in the following manner:

“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 1 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 5 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.”

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In 2010, the Centers for Medicare & Medicaid Services also issued 2 decision memos on specific programs. One stated that the Ornish Program for Reversing Heart Disease met the intensive cardiac rehabilitation program requirements and was included on the list of approved intensive cardiac rehabilitation programs. It provided the following description of the Ornish Program: “The Ornish Program for Reversing Heart Disease (also known as the Multisite Cardiac Lifestyle Intervention Program, Multicenter Cardiac Lifestyle Intervention Program and the Lifestyle Heart Trial program) ... 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.”

The other stated that the Pritikin Program met program requirements and was included on the list of approved intensive cardiac rehabilitation programs. As described in the decision memo: “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% to 15% of calories from fat, 15% to 20% from protein, 65% to 75% from complex carbohydrates), exercise and counseling lasting 21 to 26 days. An optional residential component is also available for participants.”

In 2014, Centers of Medicare & Medicaid Services issued another decision memo on the Benson-Henry Institute Cardiac Wellness Program. The memo stated that "the evidence is sufficient to expand the intensive care rehabilitation benefit to include the Benson-Henry Institute Cardiac Wellness Program. The Cardiac Wellness Program is a multicomponent intervention program that includes supervised exercise, behavioral interventions, and counseling, and is designed to reduce cardiovascular risk and improve health outcomes."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			

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NCT No.	Trial Name	Planned Enrollment	Completion Date
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 Quality of Life (Heart-ROCQ) - A Prospective Randomized Open Controlled Trial, Blinded End-point (PROBE)	350	Aug 2025
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

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NCT: national clinical trial.

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- 09/07/2017 Medical Policy Committee review
- 09/20/2017 Medical Policy Implementation Committee approval. New policy.
- 09/06/2018 Medical Policy Committee review
- 09/19/2018 Medical Policy Implementation Committee approval. No change to coverage.
- 09/05/2019 Medical Policy Committee review
- 09/11/2019 Medical Policy Implementation Committee approval. No change to coverage.
- 09/03/2020 Medical Policy Committee review
- 09/09/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 09/02/2021 Medical Policy Committee review
- 09/08/2021 Medical Policy Implementation Committee approval. Added PICO and investigational policy statement for intensive cardiac rehabilitation with the Benson-Henry Institute Program.
- 09/01/2022 Medical Policy Committee review

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- 09/14/2022 Medical Policy Implementation Committee approval. No change to coverage.
- 05/04/2023 Medical Policy Committee review
- 05/10/2023 Medical Policy Implementation Committee approval. Added “Based on review of available data, the Company considers virtual cardiac rehabilitation to be investigational.”
- 05/02/2024 Medical Policy Committee review
- 05/08/2024 Medical Policy Implementation Committee approval. Investigational policy statement added for all other indications, including post-acute sequelae of SARS-CoV-2 infection.

Next Scheduled Review Date: 05/2025

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	93797, 93798
HCPCS	G0422, G0423, S9472
ICD-10 Diagnosis	All related diagnoses

***Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

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- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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