



# Louisiana

## Cardiac Rehabilitation in the Outpatient Setting

Policy # 00570

Original Effective Date: 09/20/2017

Current Effective Date: 08/01/2023

*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**.\*

## **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 2023 update on heart disease and stroke statistics from the American Heart Association, it was estimated that

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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 individuals.” The U.S. Public Health Service recommended cardiac rehabilitation services for individuals 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 individuals.” 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.

## **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

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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 individuals 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 individuals, 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 it with usual care. The trial included individuals 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 individuals 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

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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 been diagnosed with heart disease and receive virtual cardiac rehabilitation, the evidence includes systematic reviews/meta-analyses, RCTs, and retrospective 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 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

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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**

In 2013, the American College of Cardiology Foundation and the American Heart Association updated their joint guidelines on the management of heart failure. These guidelines included the following class IIA recommendation on cardiac rehabilitation (level of evidence: B): “Cardiac rehabilitation can be useful in clinically stable individuals with heart failure to improve functional capacity, exercise duration, health-related quality of life, and mortality.” The 2022 guideline from the same organizations did not include additional information on cardiac rehabilitation.

### **American College of Physicians**

In 2012, the American College of Physicians and 6 other cardiology associations published joint guidelines on the management of stable ischemic heart disease. The guidelines included the following statement on cardiac rehabilitation: “Medically supervised exercise programs (cardiac rehabilitation) and physician-directed, home-based programs are recommended for at-risk individuals at first diagnosis.” The 2014 update to the guideline did not include additional information on cardiac rehabilitation.

### **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 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

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on home-based cardiac rehabilitation (HBCR). They make the following suggestions for healthcare providers:

- Recommend center-based cardiac rehabilitation (CBCR) to all eligible individuals.
- As an alternative, recommend HBCR to clinically stable low- and moderate-risk individuals 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 individuals to follow personalized recommendations for exercise, dietary, and behavioral interventions, and thus expand the number of individuals 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**

Not applicable.

### **Medicare National Coverage**

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### **Cardiac Rehabilitation**

Since 1989, Medicare has had a national coverage determination for cardiac rehabilitation. In 2010, there was a change in Medicare coverage for cardiac rehabilitation. Indications for coverage remained the same; namely, individuals who have experienced at least 1 of the following:

- Acute myocardial infarction within the preceding 12 months
- Coronary artery bypass surgery
- Current stable angina pectoris
- Heart valve repair or replacement
- Percutaneous transluminal coronary angioplasty or coronary stenting
- Heart or heart-lung transplant

As of February 2014, patient eligibility criteria were expanded for cardiac rehabilitation to include individuals with the following: “Stable, chronic heart failure, defined as individuals 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. Stable individuals are defined as individuals who have not had recent ( $\leq 6$  weeks) or planned ( $\leq 6$  months) major cardiovascular hospitalizations or procedures.”

The 2010 criteria specify the required components of cardiac rehabilitation programs. Programs must include all of the following:

- “Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished;
- Cardiac risk factor modification, including education, counseling, and behavioral intervention at least once during the program, tailored to individuals’ individual needs;
- Psychosocial assessment;
- Outcomes assessment; and
- An individualized treatment plan detailing how components are utilized for each patient.”

In January 2010, the criteria on the frequency and duration of cardiac rehabilitation services were updated:

“Cardiac rehabilitation items and services must be furnished in a physician’s office or a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all time items and services are being furnished under the program....

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...[C]ardiac rehabilitation program 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 of an additional 36 sessions over an extended period of time if approved by the Medicare contractor.”

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 2023.

### **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 individuals: (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 individuals 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.”

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

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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>			
NCT04245813	Effectiveness of a Cardiac Rehabilitation Program in Individuals With Heart Failure	144	May 2023
NCT02984449	Preventive Heart Rehabilitation in Individuals Undergoing Elective Open Heart Surgery to Prevent	350	Aug 2025

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NCT No.	Trial Name	Planned Enrollment	Completion Date
	Complications and to Improve 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 Individuals With Post-myocardial Infarction: A Randomized Controlled Trial	124	Dec 2023
NCT05689385	The Effectiveness of eHealth-based Cardiac Rehabilitation in Post-myocardial Infarction Individuals : a Randomized Controlled Trial	150	Dec 2024
NCT05610358	Efficacy of Smartphone Application Based Rehabilitations in Individuals With Chronic Respiratory or Cardiovascular Disease	162	Dec 2024
NCT02791685	Smartphone Delivered In-home Cardiopulmonary Rehabilitation	300	Dec 2026
<i>Unpublished</i>			
NCT03218891	Cardiac Rehabilitation in Individuals With Refractory Angina	72	Feb 2022
NCT05489913	The Effect of Web Based Cardiac Rehabilitation Support on the Healthy Lifestyle Behaviors, Medication Adherence and Quality of Life in Coronary Artery Individuals	70	Jun 2021

NCT: national clinical trial.

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### **Policy History**

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Current Effective Date: 08/01/2023

- |            |  |
|------------|--|
| 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  |

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- 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
- 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.”

Next Scheduled Review Date: 05/2024

### **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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CPT is a registered trademark of the American Medical Association.

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;

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- 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
- 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.

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