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 patients 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

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 patient 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 or Pritikin Program to be **investigational.***

Background/Overview

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 with 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.

Rationale/Source

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.

For individuals who have diagnosed heart disease who receive outpatient cardiac rehabilitation, the evidence includes multiple randomized controlled trials (RCTs) and systematic reviews of these trials. Relevant outcomes are overall survival, 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 a meaningful improvement in the net health outcome.

For individuals who have diagnosed heart disease without a second event who receive repeat outpatient cardiac rehabilitation, the evidence includes no trials. Relevant outcomes are overall survival, 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 the effects of the technology on health outcomes.

For individuals who have diagnosed heart disease who receive intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease, the evidence includes an RCT 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 the effects of the technology on health outcomes.

For individuals who have diagnosed heart disease who receive intensive cardiac rehabilitation with the Pritikin Program, the evidence includes a case series. Relevant outcomes are overall survival, 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

American College of Cardiology Foundation et al

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 patients with heart failure to improve functional capacity, exercise duration, health-related quality of life, and mortality." The 2017 focused update of the guideline 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 patients at first diagnosis." The 2014 update to the guideline did not include additional information on cardiac rehabilitation.

American Heart Association et al
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 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. 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 secondary prevention."
- For healthcare organizations, develop and support the following:
    - Maximization of 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 evidence-based hybrid approached 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."

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage

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, patients 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 patients with the following: "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. Stable patients are defined as patients who have not had recent (≤ 6 weeks) or planned (≤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 patients' 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[1]:

> "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….
>
> …[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."

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 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 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."

In 2010, 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%-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."

Ongoing and Unpublished Clinical Trials
Some currently 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
Ongoing			
NCT03385837	Activity Level and Barriers to Participate of Cardiac Rehabilitation in Advanced Heart Failure Patients	50	Dec 2018

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT02762825	Novel Cardiac Rehabilitation in Patients Heart Failure and Preserved Ejection Fraction	66	Sep 2020
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
Unpublished			
NCT01822769	Cardiopulmonary Rehabilitation for Adolescents and Adults With Congenital Heart Disease	28	Dec 2017 (last updated 01/25/18)
NCT03385837	Activity Level and Barriers to Participate of Cardiac Rehabilitation in Advanced Heart Failure Patients	50	Dec 2018 (unknown; last updated 12/12/17)
NCT02619422	Multicenter, Prospective, Randomized, Open, Blinded for the End Point Evaluator to Compare Compliance to Secondary Prevention Measures After Acute Coronary Syndrome and Intensive Cardiac Rehabilitation Program vs. Standard Program	509	Feb 2018 (last updated 06/06/18)

NCT: national clinical trial.

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Policy History

Original Effective Date: 09/20/2017
Current Effective Date: 10/12/2020

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.

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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.
Next Scheduled Review Date: 09/2021

Coding

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Code Type	Code
CPT	93797, 93798

HCPCS	G0422, G0423, S9472
ICD-10 Diagnosis	I20.8-I20.9, I21.01-I21.4, I50.1-I50.9, Z94.1, Z94.3, Z95.1-Z95.5, Z98.61

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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
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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