



## FEP Medical Policy Manual

### FEP 8.03.08 Cardiac Rehabilitation in the Outpatient Setting

**Annual Effective Policy Date: July 1, 2024**

**Original Policy Date: March 2012**

**Related Policies:**

None

## Cardiac Rehabilitation in the Outpatient Setting

### Description

#### Description

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.

#### OBJECTIVE

The objective of this evidence review is to determine whether outpatient cardiac rehabilitation programs improve the net health outcome in individuals with heart disease.

## POLICY STATEMENT

Outpatient cardiac rehabilitation programs may be considered **medically necessary** for individuals with a history of the following conditions and procedures:

- 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.

Repeat participation in an outpatient cardiac rehabilitation program in the absence of another qualifying cardiac event is considered **investigational**.

Intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease, Pritikin Program, or Benson-Henry Institute Program is considered **investigational**.

Virtual cardiac rehabilitation is considered **investigational**.

Outpatient cardiac rehabilitation is considered **investigational** for all other indications (e.g., SARS-CoV-2).

## POLICY GUIDELINES

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
- an 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 and be completed within 6 months of the cardiac event.

A comprehensive evaluation may be performed before the 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.

## BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Cardiac rehabilitation must be performed in a facility approved by the Plan.

Services that are educational in nature (eg, lectures or counseling), which are performed as part of the cardiac rehabilitation program, are not eligible for coverage, even when occurring on a different date of service unless specified in the contract or certificate of coverage.

Psychological testing and psychotherapy are not usual components of cardiac rehabilitation. Such services for patients who have a psychiatric diagnosis must be considered under the Mental Health Benefits of the contract.

The ongoing maintenance program that follows the 12-week rehabilitation program is not eligible for coverage.

Some contracts have an exclusion for cardiac rehabilitation because this is considered "self-care" or "self-help" training. In these cases, any related diagnostic testing must also be excluded.

## FDA REGULATORY STATUS

Not applicable.

## RATIONALE

### 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 an 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 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 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."<sup>48</sup> 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."<sup>49</sup>

#### 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.<sup>2</sup> 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).<sup>50</sup> 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

Not applicable.

## 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.<sup>51</sup>

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.<sup>52</sup> Virtual cardiac rehabilitation will continue to be covered through the end of 2024.<sup>53,54</sup>

### 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.<sup>55</sup>

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."

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.<sup>55</sup> 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.<sup>56</sup> 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.<sup>57</sup> 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."

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## **POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:**

<b>Date</b>	<b>Action</b>	<b>Description</b>
March 2012	New policy	
December 2012	Replace policy	Bulleted list in first policy statement changed to say "or€š rather than "and€š: Policy guidelines changed to indicate that it is "preferable€š that the program start within 90 days of the cardiac event to eliminate any conflict with the time-frame in the policy statement. Rationale and References updated.
September 2013	Replace policy	Policy updated with literature review, References 3 and 9 added. Other references renumbered or removed. No change to policy statements.
September 2014	Replace policy	Policy updated with literature review, adding references 1,2,5,6, 13 and 14. No change to policy statements.
September 2015	Replace policy	Policy updated with literature review through May 12, 2015; reference 18 added. Policy statements unchanged.
March 2016	Archive policy	Policy updated with literature review; reference 8 added. Policy archived.
March 2019	Reinstate policy	Policy updated with literature review through January 26, 2018; references 11, 13-14, 16 and 22-23 added. Statement added that Intensive cardiac rehabilitation with the Pritikin Program or the Ornish Program is considered investigational; policy statements otherwise unchanged.
June 2019	Replace policy	Policy updated with literature review through January 6, 2019; references added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through January 13, 2020; reference added. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through January 20, 2021; references added. Added PICO and investigational policy statement for intensive cardiac rehabilitation with the Benson-Henry Institute Program.
June 2022	Replace policy	Policy updated with literature review through February 3, 2022; reference added. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through February 7, 2023; references added. Added PICO and investigational policy statement for virtual cardiac rehabilitation.
June 2024	Replace policy	Policy updated with literature review through January 23, 2024; references added. Investigational policy statement added for all other indications, including post-acute sequelae of SARS-CoV-2 infection.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.