FEP Medical Policy Manual

FEP 8.03.08 Cardiac Rehabilitation in the Outpatient Setting

Effective Policy Date: **July 1, 2020**

Original Policy Date: **March 2012**

Related Policies:

None

Cardiac Rehabilitation in the Outpatient Setting

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 patients with heart disease.

POLICY STATEMENT

Outpatient cardiac rehabilitation programs are considered **medically necessary** for patients 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 or Pritikin Program is considered **investigational**.

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
- 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 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.

BENEFIT APPLICATION

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

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 a usual component of cardiac rehabilitation.

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

FDA REGULATORY STATUS

Not applicable.

RATIONALE

Summary of Evidence

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.[20] 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.[21]

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.[22] 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.[23]

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.[5] 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.[24] 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.[25] 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."[26]

The 2010 criteria specify the required components of cardiac rehabilitation programs. Programs must include all of the following[25]:

- "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[25]:

"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.[25]

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.[27] 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.[27] 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."

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

Date	Action	Description
March 2012	New policy	
December 2012	Replace policy	Bulleted list in first policy statement changed to say "or" rather than "and": Policy guidelines changed to indicate that it is "preferable" 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.