



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

## Cardiac Rehabilitation in the Outpatient Setting

**Policy Number:** 8.03.08

**Last Review:** 9/2014

**Origination:** 12/1990

**Next Review:** 9/2015

### **Policy**

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Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for cardiac rehabilitation when it is determined to be medically necessary because the criteria shown below are met.

### **When Policy Topic is covered**

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Cardiac rehabilitation programs are considered **medically necessary** for patients with a history of the following procedures:

- acute myocardial infarction (MI, "heart attack") within the preceding 12 months;
- coronary artery bypass graft (CABG) surgery;
- percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting;
- heart valve surgery;
- heart or heart-lung transplantation;
- current stable angina pectoris;
- compensated heart failure.

### **When Policy Topic is not covered**

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

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

### **Considerations**

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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 prior to initiation of cardiac rehabilitation to evaluate the patient and determine an appropriate exercise program. In addition to a medical examination, an EKG stress test may be performed. An additional stress test may be performed at the completion of the program.

Services that are educational in nature, e.g., 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 specifically specified in the contract or certificate of coverage.

Psychological testing and psychotherapy are not a usual component 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, as this is considered “self-care” or “self-help” training. In these cases, any related diagnostic testing must also be excluded.

Cardiac rehabilitation is covered if provided by the outpatient department of a hospital or in a physician directed clinic that has all the necessary cardio-pulmonary emergency diagnostic and therapeutic life saving equipment available for immediate use.

The following services are considered included in the charges for a comprehensive cardiac rehabilitation program:

- **Stress Testing** - ECG stress test (treadmill or bicycle ergometer) with physician monitoring and report. This is routinely available for three (3) times during the course of the program: One at the beginning, one in the middle to determine progress and one at the completion of the program.
- **Physician Monitoring** - A brief or limited examination for physician follow-up to adjust medication or make other treatment changes. Physician monitoring would also include telemetric monitoring during exercise is covered up to a maximum of three (3) visits per week.
- **Education and Counseling** - related to diet, nutrition, stress, psychological problems, sexual activity, etc.
- **Stress Management Program** - This program teaches patients principles of relaxation and managing stress, a form of biofeedback.
- **Maintenance Program (Phase III)** - The on-going exercise and support program that follows successful completion of a 12-week rehabilitation program.

### **Description of Procedure or Service**

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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 recently specified core components to be included in cardiac rehabilitation programs.

Heart disease is the leading cause of mortality in the U.S., causing more than half of all deaths. Coronary artery disease (CAD) is the most common cause of heart disease. Annually, it is estimated that 785,000 Americans suffer a new myocardial infarction (MI), and 470,000 have a recurrent MI.(1) In addition, CAD can lead to the clinical syndrome of heart failure, which occurs in about 650,000 new cases in the U.S. annually.(2) Heart failure may be secondary to or coexist with CAD, but can also be related to structural heart disease and other genetic, metabolic, endocrine, toxic, inflammatory, and infectious causes. Given the disease 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.

In 1995, the U.S. Public Health Service (USPHS) 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.”(3) This USPHS guideline 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 by the Cardiac Rehabilitation Section of the European Association of Cardiovascular Prevention and Rehabilitation is

as follows: “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.”(4) Since the release of the USPHS guideline, other societies, including the American Heart Association(5) and the Heart Failure Society of America(6) have developed guidelines about the role of cardiac rehabilitation in patient care.

Note: This policy does not address programs considered to be “Intensive Cardiac Rehabilitation Programs,” such as the Dean Ornish Program for Reversing Heart Disease and the Pritikin Program.

## **Rationale**

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The policy was created in 1997 with a literature review using MEDLINE and incorporated a clinical practice guideline on cardiac rehabilitation issued by the U.S. Department of Health and Human Services in 1995.(3) The policy was on “no further review” status from 2003 to 2010, at which time it returned to active review. The most recent literature review was from May 2013 through May 12, 2014. The following is a description of the key literature to date.

## **Literature Review**

### ***Does outpatient cardiac rehabilitation improve outcomes for patients with heart disease?***

Many randomized controlled trials (RCTs) have been published comparing cardiac rehabilitation with usual care for patients with established heart disease, and a number of meta-analyses of RCTs have been performed. In 2012, Oldridge identified 6 independent meta-analyses published since 2000 that reported outcomes from RCTs after cardiac rehabilitation interventions.(7) The RCTs included in the meta-analyses enrolled patients with myocardial infarction (MI), coronary heart disease (CHD), angina, percutaneous coronary intervention, and/or coronary artery bypass graft (CABG). RCTs compared cardiac rehabilitation programs (exercise only and/or comprehensive rehabilitation) with usual care. Cardiac rehabilitation was associated with a statistically significant ( $p < 0.05$ ) reduction in all-cause mortality in 4 of the 5 meta-analyses that reported this outcome. In addition, cardiac rehabilitation was associated with a statistically significant reduction in cardiac mortality in 3 of the 4 meta-analyses that reported disease-specific mortality as an outcome.

Two of the meta-analyses on cardiac rehabilitation were conducted by the Cochrane collaboration. One of these included patients with CHD and the other focused on patients with systolic heart failure.(8,9) Both reviews addressed exercise-based cardiac rehabilitation programs (exercise-alone or as part of comprehensive program). In 2011, Heran et al identified 47 RCTs with a total of 10,794 patients comparing cardiac rehabilitation with usual care in patients with CHD.(8) Seventeen of the studies used exercise-only interventions, and 29 used comprehensive rehabilitation (ie, exercise plus psychosocial and/or educational interventions). Most studies (32/47 [68%]) were conducted in Europe. Trial sample size ranged from 28 to 2304. The median duration of rehabilitation interventions was 3 months, and there was a median follow-up duration of 24 months. The investigators reported that most studies had limited information available on methodologic quality. Due to the nature of the intervention, patients were not blinded to treatment group in any of the studies. Only 4 studies reported that there was blinded assessment of study outcomes. In a pooled analysis of data from 17 trials reporting all-cause mortality after at least 12 months of follow-up, cardiac rehabilitation resulted in a significantly lower mortality rate compared with usual care (relative risk [RR], 0.87; 95% confidence interval [CI], 0.75 to 0.99). Similarly, a pooled analysis of findings from 12 trials with at least 12 months' follow-up found a significantly lower rate of cardiovascular mortality in the cardiac rehabilitation compared with the usual care group (RR=0.74; 95% CI, 0.63 to 0.87). In sensitivity analyses of a priori defined variables, the investigators did not find a significant association between health outcomes and the type of cardiac rehabilitation (ie, exercise-only vs comprehensive cardiac rehabilitation), length of the intervention or study publication date (ie, published before 1995 or 1995 and later).

The 2010 Cochrane review by Davies et al identified a total of 19 trials with 3647 heart failure patients; 1 large trial, HF-ACTION, contributed 2331 (60%) patients.(9) The overall quality of the studies was

judged to be poor; for example, only 3 studies adequately described their randomization process, and only 3 studies had blinded outcome assessment. A pooled analysis of the 13 studies reporting all-cause mortality with up to 12 months' follow-up, did not find a statistically significant difference in mortality between groups (RR=1.02; 95% CI, 0.70 to 1.51). Similarly, there was not a significant difference between groups in all-cause mortality in a pooled analysis of the 4 studies reporting more than 12 months' follow-up (RR=0.88; 95% CI, 0.73 to 1.07). No significant between-group differences were found for the other primary outcome variable, hospital admissions. For example, when findings from 5 studies reporting hospital admissions up to 12 months were pooled, the relative risk was 0.79 (95% CI, 0.58 to 1.07). Most of the studies included in the Cochrane review, including the HF-ACTION trial, were exercise-only interventions; thus, conclusions cannot be drawn from this review regarding the impact of comprehensive cardiac rehabilitation programs on mortality or hospital admissions in patients with heart failure. The Cochrane review did not require that studies only included patients with compensated heart failure.

A 2011 meta-analysis by Lawler et al addressed exercise-based cardiac rehabilitation programs for patients who had a recent MI.(10) To be included in the review, trials needed to include a minimum intervention duration of 2 weeks and a minimum of 12 weeks of follow-up. Interventions could involve any form of exercise program, with or without other interventions. A total of 34 RCTs with 6111 patients met the review's inclusion criteria. In a pooled analysis of data from 18 trials, patients randomized to cardiac rehabilitation had a significantly lower risk of reinfarction than patients randomized to a control condition (odds ratio [OR], 0.53; 95% CI, 0.38 to 0.76). There was also a lower risk of all-cause mortality (OR=0.74; 95% CI, 0.58 to 0.95) and cardiovascular mortality (OR=0.60; 95% CI, 0.40 to 0.76) in the group randomized to cardiac rehabilitation compared with a control intervention.

Findings of a large, multicenter RCT from the U.K. that evaluated the effectiveness of cardiac rehabilitation in a 'real-life' setting were published by West et al in 2012.(11) Called the Rehabilitation After Myocardial Infarction Trial (RAMIT), the study included patients from centers with established cardiac rehabilitation programs that were multifactorial (including exercise, education, counseling), involved more than 1 discipline, and provided an intervention lasting a minimum of 10 hours. A total of 1813 patients from 14 centers were randomized, 903 to cardiac rehabilitation and 910 to a control condition. Vital status was obtained at 2 years for 99.9% of participants (all but 1 patient) and at 7 to 9 years for 99.4% of participants. By 2 years, 166 patients had died, 82 (9.1%) in the cardiac rehabilitation group and 84 (9.2%) in the control group. The between-group difference in mortality at 2 years (the primary study outcome) was not statistically significant (RR=0.98; 95% CI, 0.74 to 1.30). After 7 to 9 years, 488 patients had died, 245 (27%) in the cardiac rehabilitation group and 243 (26.7%) in the control group (RR=0.99; 95% CI, 0.85 to 1.15). In addition, at 2 years, cardiovascular morbidity did not differ significantly between groups. For a combined end point including death, nonfatal MI, stroke or revascularization, the relative risk was 0.96 (95% CI, 0.88 to 1.07). In discussing the study's negative findings, the trial authors noted that medical management of heart disease has improved over time, and patients in the control group may have had better outcomes than in earlier RCTs on this topic. Moreover, an editorial accompanying publication of study findings emphasized that RAMIT was not an efficacy trial but instead a trial evaluating the effectiveness of actual cardiac rehabilitation programs in the U.K.(12) Finally, these results may in part reflect the degree to which clinically based cardiac rehabilitation programs in the U.K. differ from the treatment protocols used in RCTs that were based in research settings.

A concern raised by the negative findings in the RAMIT trial is that most of the RCTs evaluating cardiac rehabilitation were conducted in an earlier era of heart disease management and may not be relevant to current care. Although no new RCT evidence was identified, several newer nonrandomized studies have been published since the RAMIT trial that corroborate prior RCT evidence about the benefit of cardiac rehabilitation after MI. Two examples of such studies are provided here.

In 2013, Pack et al assessed the association between cardiac rehabilitation attendance and outcomes among 846 patients in a single Minnesota county who underwent CABG from 1996 to 2007.(13) After

propensity score adjustment, attending cardiac rehabilitation was associated with a reduced risk of 10-year mortality (hazard ratio [HR], 0.54; 95% CI, 0.01 to 0.74;  $p < 0.001$ ).

In a longitudinal observational study, Coll-Fernandez et al compared mortality and subsequent ischemic event rates after acute MI between patients who underwent cardiac rehabilitation ( $n=521$ ) and those who did not ( $n=522$ ).<sup>(14)</sup> In multivariate analysis, patients who underwent cardiac rehabilitation had lower mortality than those who did not (adjusted HR=0.08; 95% CI, 0.01 to 0.63;  $p=0.016$ ).

Although these nonrandomized studies published since the RAMIT trial are limited by the potential for residual confounding by unobserved variables even after propensity-score adjustment or multivariable adjustment, they provide some additional evidence supporting the use of cardiac rehabilitation in the current era of cardiac care.

### ***Does repeat outpatient cardiac rehabilitation improve outcomes?***

No studies were identified that evaluated the effectiveness of repeat participation in a cardiac rehabilitation program.

### **Ongoing Clinical Trials**

A search of online database [ClinicalTrials.gov](http://ClinicalTrials.gov) on May 15, 2014 using the term “cardiac rehabilitation” as the intervention identified the following randomized studies that are currently enrolling patients:

- Enhancing Standard Cardiac Rehabilitation With Stress Management Training in Patients With Heart Disease (ENHANCE) (NCT00981253) – This is a randomized, open-label trial designed to evaluate whether cardiac rehabilitation incorporating exercise and stress management is more effective than standard cardiac rehabilitation at improving cardiac biomarkers among patients with a diagnosis of CHD who are eligible for cardiac rehabilitation. Enrollment is planned for 150 subjects; the planned study completion date is May 2014.
- Multi-Disciplinary Rehabilitation Program in Recently Hospitalized Patients With Preserved Ejection Fraction Heart Failure (NCT01914315) – This is a randomized, single-blinded (outcomes assessor-blinded) study to evaluate whether comprehensive cardiac rehabilitation is superior to standard care for patients with heart failure with preserved systolic function who are discharged after an acute heart failure event. Enrollment is planned for 1100 subjects; the planned study completion date is January 2016.
- OPTimal CARDiac REhabilitation (OPTICARE) Following Acute Coronary Syndromes: A Randomized, Controlled Trial to Investigate the Benefits of an Expanded Educational and Behavioural Intervention Program (NCT01395095) – This is a randomized, open-label trial designed to compare 2 extended cardiac rehabilitation programs to a standard cardiac rehabilitation program among patients with acute coronary syndrome treated with primary or elective percutaneous coronary intervention or coronary surgery. Enrollment is planned for 1200 subjects; the planned study completion date is March 2016.
- Effects of Homebased Training With Telemonitoring Guidance in Low to Moderate Risk Patients Entering Cardiac Rehabilitation (NCT01732419) – This is a randomized, open label trial to compare home-based cardiac rehabilitation with center-based cardiac rehabilitation among patients with acute coronary syndrome or a cardiac revascularization procedure. Enrollment is planned for 90 subjects; the planned study completion date is October 2014.
- Efficacy of Physical Exercise in Cardiac Rehabilitation (NCT01617850) – This is a randomized, single-blinded trial to compare an “optimized” (higher-intensity) exercise program to a conventional program for improvement in exercise-related parameters among patients with angina pectoris, acute MI, and chronic heart failure. Enrollment is planned for 70 subjects; the study completion date was listed as December 13, 2013. No results have been published.
- Cardiopulmonary Rehabilitation for Adolescents and Adults With Congenital Heart Disease (NCT01822769) – This is a randomized, single-blinded trial to compare a formal 12-week outpatient cardiac rehabilitation program with standard care for adults and children with congenital heart

disease and impaired aerobic capacity. Enrollment is planned for 60 subjects; the planned study completion date is December 2014.

## Summary

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. A joint national U.S. guideline has specified core components of cardiac rehabilitation programs. Numerous randomized controlled trials (RCTs) have been performed, and meta-analyses of RCTs have found that cardiac rehabilitation improves health outcomes for selected patients. The evidence is insufficient to support repeat participation in cardiac rehabilitation programs.

## Practice Guidelines and Position Statements

In 2013, the American College of Cardiology Foundation and the American Heart Association published updated guidelines on the management of heart failure.<sup>(2)</sup> These guidelines include the following Class IIA recommendation related to cardiac rehabilitation (Level of Evidence: B): *Cardiac rehabilitation can be useful in clinically stable patients with HF [heart failure] to improve functional capacity, exercise duration, HRQOL [health-related quality of life], and mortality.*

In 2012, the American College of Physicians, American College of Cardiology Foundation, American Heart Association/American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association and Society of Thoracic Surgeons published a joint guideline on management of stable ischemic heart disease.<sup>(15)</sup> The guideline included the following statement on cardiac rehabilitation:

*Medically supervised exercise programs, i.e., cardiac rehabilitation and physician-directed home-based programs, are recommended for at-risk patients at first diagnosis of stable ischemic heart disease.*

In 2007, the American Heart Association and American Association of Cardiovascular and Pulmonary Rehabilitation issued an updated consensus statement on the core components of cardiac rehabilitation programs.<sup>(16)</sup> The 10 core components are: *patient assessment prior to 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 offer supervised exercise training are not considered to be cardiac rehabilitation.* The updated guidelines specify the assessment, interventions, and expected outcomes for each of the core components. For example, symptom-limited exercise testing before exercise training is strongly recommended. The national guideline does not specify the optimal overall length of programs or number or duration of sessions.

In 2010, Cardiac Rehabilitation Section of the European Association of Cardiovascular Prevention and Rehabilitation published a position paper on cardiac rehabilitation.<sup>(4)</sup> Recommendations were based on a review of national guidelines from the U.S. and Europe. They stated that core components of cardiac rehabilitation are patient assessment, physical activity counseling, exercise training, diet/nutritional counseling, weight-control management, lipid management, blood pressure monitoring, smoking cessation, and psychosocial management. The recommended criteria for adequate exercise training are:

- Mode: Continuous endurance e.g., walking, jogging, cycling, swimming, etc.
- Duration: At least 20-30 minutes (preferably 45-60 minutes)
- Frequency: Most days (at least 3 days per week and preferably 6-7 days per week)
- Intensity: 50%-80% of peak oxygen consumption or of peak heart rate or 40%-60% of heart rate reserve.

The position paper did not address repeat participation in cardiac rehabilitation programs.

## Medicare National Coverage

There was a change in Medicare coverage for cardiac rehabilitation as of January 1, 2010.(17) Indications for coverage remain the same; namely, patients who have experienced at least one 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 (PTCA) or coronary stenting
- Heart or heart-lung transplant

The new 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
- Individualized treatment plan detailing how components are utilized for each patient.

In addition, criteria on the frequency and duration of cardiac rehabilitation services were updated. On or before December 31, 2009, Medicare covered 18 weeks of cardiac rehabilitation services, with contractor discretion to cover services beyond 18 weeks. Coverage could not exceed a total of 72 sessions for 36 weeks.

Beginning January 1, 2010, the criteria are: "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....cardiac rehabilitation program sessions are limited to a maximum of two 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."

Also, beginning on January 1, 2010, Medicare added intensive cardiac rehabilitation as a benefit. Intensive cardiac rehabilitation programs must be approved by Medicare on an individual basis.(18)

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### **Billing Coding/Physician Documentation Information**

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<b>S9472</b>	Cardiac rehabilitation program, non-physician provider, per diem
<b>93015</b>	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; with physician supervision, with interpretation and report
<b>93016</b>	Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress; physician supervision only, without interpretation and report
<b>93797</b>	Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)
<b>93798</b>	Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)

### **Additional Policy Key Words**

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N/A

### **Policy Implementation/Update Information**

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12/1/90	New policy.
6/1/00	No policy statement changes.

6/1/01	Policy statement revised to include: chronic stable angina as medically necessary with criteria; and cardiac rehab for CHF requires medical director approval; and Phase III rehab is not eligible for coverage. Prior authorization requirement added.
6/1/02	No policy statement changes.
1/1/03	No policy statement changes. Prior authorization requirement is removed.
6/1/03	No policy statement changes.
6/1/04	Policy statement revised to require the program to begin within 90 days of the event and be completed within 6 months of the cardiac event (previously, the cardiac event was required within 6 months).
6/1/05	Policy statement revised to remove medical director approval requirement for CHF.
6/1/06	No policy statement changes.
6/1/07	No policy statement changes.
6/1/08	No policy statement changes.
6/1/09	No policy statement changes.
6/1/10	No policy statement changes.
10/1/10	Changes to existing medically necessary policy statement included the addition of the indications heart-lung transplantation and coronary stenting, and specification of components in cardiac rehabilitation programs; second policy statement that repeat programs are investigational added. "In the outpatient setting" added to policy title.
6/1/11	No policy statement changes.
6/1/12	No policy statement changes.
6/1/13	No policy statement changes.
9/1/13	No policy statement changes.
9/1/14	No policy statement changes.

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