Title: Cardiac Rehabilitation, Outpatient

Description/Background

HEART DISEASE
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 2015 update on heart disease and stroke statistics from the American Heart Association, it was estimated that 635,000 Americans have a new coronary attack (first hospitalized myocardial infarction or coronary heart disease death) and 300,000 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 U.S. 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 re-infarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process and enhance the psychosocial and vocational status of selected patients.” This 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 release of the U.S. Public Health Service guidelines, other societies, including the American Heart...
Association (2005)\(^4\) and the Heart Failure Society of America (2010)\(^5\) have developed guidelines about the role of cardiac rehabilitation in patient care.

Cardiac rehabilitation consists of the evaluation of a cardiac patient and the individualized prescription by a qualified physician of graded active exercise designed to strengthen the heart muscle. The patient is instructed in performance of the exercises, self-monitoring of blood pressure and signs of cardiac dysfunction. The patient may also receive instruction concerning nutrition, risk factors and lifestyle modification.

Cardiac rehabilitation programs are divided into three or more stages or phases:
- **Phase I**—Inpatient evaluation, including risk assessment, medication and diet education, early mobilization and discharge planning.
- **Phase II**—Post discharge evaluation and physical assessment which then focuses on continued health education and the return to physical activity which is structured and supervised for a period of four to six weeks. Outpatient cardiac rehabilitation sessions are generally limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks, with the option for an additional 36 sessions over an extended period of time if approved.
- **Phase III**—Prescribed exercise regimen performed by the patient, in the home or independent gym that does not require the presence or close supervision of a therapist or physician.
- **Phase IV**—The patient continues the prescribed exercise regimen at a cardiac rehab center where there is access to supervision, continued education and counseling.

**Note:** This policy does not address programs considered to be intensive cardiac rehabilitation. Refer to the policy titled, “Intensive Cardiac Rehabilitation.”

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**Regulatory Status**

N/A

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**Medical Policy Statement**

Short-term outpatient Phase II cardiac rehabilitation is established as safe and effective and is an accepted standard therapy in patient with a history of specific cardiac conditions or procedures.

Cardiac rehabilitation must be a physician-supervised program that furnishes a prescribed exercise program, cardiac risk factor modification that includes education, counseling, and behavioral intervention as well as psychosocial assessment and outcomes assessment.
Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Inclusions:
Must meet all:
- Phase II cardiac rehabilitation
- Member must be medically stable and able to tolerate exercise for 20-40 minutes.
- Must have a least one diagnosis (documented within the last 12 months) listed below:
  - Acute myocardial infarction
  - Coronary artery bypass graft surgery
  - Current stable angina pectoris
  - Percutaneous transluminal coronary angioplasty or coronary stenting
  - Heart valve surgery
  - Heart or heart-lung transplant
  - Compensated heart failure

Exclusions:
- Phase III cardiac rehabilitation
- Phase IV cardiac rehabilitation
- Does not meet diagnostic criteria
- Repeat participation in a cardiac rehabilitation program in the absence of another qualifying cardiac event
- Intensive cardiac rehabilitation (Refer to medical policy, “Intensive Cardiac Rehabilitation”)

CPT/HCPCS Level II Codes (Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)

Established codes:
93797 93798

Other codes (investigational, not medically necessary, etc.):
S9472

Note: Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage

Rationale
Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.
To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

OUTPATIENT CARDIAC REHABILITATION FOR HEART DISEASE

Systematic Reviews
Oldridge (2012) identified 6 independent meta-analyses published since 2000 that reported outcomes from 71 RCTs (total N=13824 patients) following cardiac rehabilitation interventions.6 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 the pooled analysis, cardiac rehabilitation was associated with an 18.5% mean reduction in all-cause mortality. 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 was conducted by Cochrane. One included patients with CHD7 and the other focused on patients with systolic heart failure.8 Both addressed exercise-based cardiac rehabilitation programs (exercise alone or as part of comprehensive program). Anderson et al (2016) updated a 2011 Cochrane review addressing exercise-based cardiac rehabilitation for individuals with CHD.7,9 Reviewers included RCTs of exercise-based interventions with at least 6 months of follow-up compared with no-exercise controls in patients with MI, CABG, or percutaneous coronary intervention, or with angina pectoris or coronary artery disease. The updated review included 63 RCTs (total N=14,486 individuals), of which 16 trials had been published since the 2011 update. Reviewers reported that the overall risk of bias was unclear, although the quality of reporting improved with more recent trials. Due to the nature of the intervention, patients were not blinded to treatment group in any of the studies, but 16 (25%) of 62 studies reported details of blinded assessment of study outcomes. In the pooled analysis, cardiac rehabilitation was not significantly associated with overall mortality. However, among 27 studies, cardiac rehabilitation was significantly associated with reduced cardiovascular mortality (292/3850 for cardiac rehabilitation subjects vs 375/3619 for control subjects; relative risk [RR], 0.74; 95% confidence interval [CI], 0.64 to 0.86). Rates of MI, CABG, and percutaneous coronary intervention were not significantly associated with receiving cardiac rehabilitation.

A Cochrane review by Taylor et al (2014) reported on studies assessing cardiac rehabilitation in patients with heart failure.10 Reviewers included 33 trials (total N=4740 individuals), with 14 studies added with the latest update. One large trial (HF-ACTION) contributed 50% of patients;
most other studies were small and single center. The population was predominantly patients with heart failure with reduced ejection fraction and New York Heart Association functional class II and III heart failure. The trials had a moderate risk of bias; many earlier studies (particularly pre-2000) had insufficient detail to permit assessment of risk of bias. In the 25 studies that reported all-cause mortality up to 12-month follow-up, there was no difference in pooled mortality between groups (RR=0.93; 95% CI, 0.69 to 1.27; p=0.59). For health-related quality of life, most studies reported disease-specific quality of life with the Minnesota Living With Heart Failure questionnaire. Although there was statistical heterogeneity in differences in the Minnesota Living With Heart Failure scores between exercise and control groups, there was a significant improvement in Minnesota Living With Heart Failure scores with exercise in pooled analysis (mean difference, -5.8; 95% CI, -9.2 to -2.4, p=0.001). Most studies selected for the Cochrane review, including the HF-ACTION trial, were exercise-only interventions; thus, conclusions cannot be drawn from this review about the impact of comprehensive cardiac rehabilitation programs on mortality or hospital admissions in patients with heart failure. Reviewers did not require that studies only include patients with compensated heart failure.

**Table 1. SR & MA Characteristics**

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N., Range</th>
<th>Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davies (2010)[8]</td>
<td>1990-2002</td>
<td>29</td>
<td>All adults with chronic HF</td>
<td>1126</td>
<td>RCT</td>
</tr>
<tr>
<td>Oldridge (2012)[6]</td>
<td></td>
<td>71</td>
<td>Patients with MI, CHD, angina, PCI, and/or CABG</td>
<td>13,824</td>
<td>RCT</td>
</tr>
<tr>
<td>Anderson (2016)[7]</td>
<td>1975-2014</td>
<td>63</td>
<td>Patients with MI, angina pectoris, CAD, or who underwent CABG or PCI</td>
<td>14,486</td>
<td>RCT</td>
</tr>
</tbody>
</table>

HF: heart failure; NR: not reported; MI: myocardial infarction; CHD: coronary heart disease; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft; CAD: coronary artery disease; PCI: percutaneous coronary 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 (2012).\textsuperscript{11} Called the Rehabilitation After Myocardial Infarction Trial (RAMIT), the study included patients from 14 centers with established multifactorial cardiac rehabilitation (including exercise, education, and counseling), involved more than 1 discipline, and provided an intervention lasting a minimum of 10 hours. A total of 1813 patients from 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 patients. By 2 years, 166 patients had died, 82 in the cardiac rehabilitation group and 84 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 in the cardiac rehabilitation group and 243 in the control group. The between-group difference in mortality at 2 years (the primary study outcome) was not statistically significant (RR=0.99; 95% CI, 0.85 to 1.15). In addition, at 1 year, cardiovascular morbidity did not differ significantly between groups. For a combined end point including death, nonfatal MI, stroke or revascularization, the RR was 0.96 (95% CI, 0.88 to 1.07). In discussing the study’s negative findings, the trialists noted that medical management of heart disease has improved over time, and patients in the control group might have had better outcomes than in earlier RCTs on this topic. Moreover, an editorial accompanying publication of the trial’s findings emphasized that RAMIT was not an efficacy trial, but rather, a trial evaluating the effectiveness of actual cardiac rehabilitation programs in the U.K.\textsuperscript{12} Finally, these results might 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.

**Table 2. SR & MA Results**

<table>
<thead>
<tr>
<th>Study</th>
<th>Increase in VO\textsubscript{2} Max</th>
<th>Reduction in All Cause Mortality</th>
<th>Cardiovascular Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davies (2010)\textsuperscript{[8]}</td>
<td>2.16 ml/kg/min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>2.82-1.49</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oldridge (2012)\textsuperscript{[6]}</td>
<td></td>
<td>18.50%</td>
<td></td>
</tr>
<tr>
<td>P-value</td>
<td>&lt;0.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taylor (2014)\textsuperscript{[10]}</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RR</td>
<td>0.93</td>
<td></td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>0.69-1.27</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P-value</td>
<td>0.59</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anderson (2016)\textsuperscript{[7]}</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RR</td>
<td>0.96</td>
<td></td>
<td>0.74</td>
</tr>
<tr>
<td>95% CI</td>
<td>0.88-1.04</td>
<td></td>
<td>0.64-0.86</td>
</tr>
</tbody>
</table>
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. However, RAMIT's results, along with 15 additional RCTs reported since a 2011 Cochrane review, were included in the updated 2016 Cochrane review, which found improvements in cardiovascular mortality associated with exercise-based cardiac rehabilitation.

Pandey et al (2017) evaluated endurance exercise training as part of a cardiac rehabilitation program in a population of heart failure patients stratified by ejection fraction. Participants had heart failure with preserved ejection fraction (HFrEF) or reduced ejection fraction, were 65 years of age or older, and had participated in a 16-week exercise program that intensified from 40% to 50% of heart rate reserve in the first 2 weeks to 60% to 70% over the ensuing weeks as part of a previously published RCT (Kitzman et al [2010]). The primary outcome for assessing change in exercise capacity was percentage change in peak oxygen uptake (VO2peak) (mL/kg per minute) from baseline to end of exercise training (16-week follow-up). Data on testing from 48 patients (24 reduced ejection fraction, 24 HFrEF) were assessed. HFrEF patients experienced greater improvement in exercise training patients (18.7%) than reduced ejection fraction patients (-0.3%; p<0.001) as measured by VO2peak. There was no information on subsequent hospitalization rates or clinical outcomes such as heart failure progression or mortality. This secondary analysis was used to assert the appropriateness of cardiac rehabilitation in HFrEF patients.

### Table 3. Summary of Key RCT Characteristics

<table>
<thead>
<tr>
<th>Study Trial</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pandey (2017) [13]</td>
<td>US</td>
<td>1</td>
<td>NR</td>
<td>Patients age 65 with either HFrEF (n=24) or HFrEF (n=24)</td>
<td>16-week supervised moderate endurance exercise training</td>
<td></td>
</tr>
</tbody>
</table>

RCT: randomized controlled trial; MI: myocardial infarction; NR: not reported; HFrEF: HF with reduced ejection fraction; HFrEF: HF with preserved ejection fraction.
### Table 4. Summary of Key RCT Results

<table>
<thead>
<tr>
<th>Study</th>
<th>X2 yr Mortality</th>
<th>Readmissions to Hospital for any Cardio Condition at 1 yr</th>
<th>Training Related Improvement in VO2peak change</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR Control</td>
<td>82 patients</td>
<td>222 (25%)</td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td></td>
<td>0.74-1.30</td>
<td></td>
</tr>
<tr>
<td>Pandey (2017) [13]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HFrEF</td>
<td></td>
<td>18.7+/−17.6</td>
<td></td>
</tr>
<tr>
<td>HFrEF</td>
<td></td>
<td>−0.3+/−15.4</td>
<td></td>
</tr>
<tr>
<td>P-value</td>
<td></td>
<td>&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

RCT: randomized controlled trial; Yr.: year; CR: cardiac rehabilitation; Cardio: cardiovascular; VO2peak: peak oxygen uptake.

### Table 5. Relevance Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Intervention</th>
<th>Comparator</th>
<th>Outcomes</th>
<th>Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>West (2012)[11]</td>
<td></td>
<td></td>
<td>2. No comparator used</td>
<td></td>
<td>1.2. Trial was closed prematurely</td>
</tr>
<tr>
<td>Pandey (2017)[13]</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.2. Only 16 weeks follow-up</td>
</tr>
</tbody>
</table>

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

- Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
- Intervention key: 1. Not clearly defined, 2. Version used unclear, 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
- Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
Observational Studies
Sumner et al (2017) published a systematic review of controlled observational studies evaluating cardiac rehabilitation in patients diagnosed with acute MI. Cardiac rehabilitation interventions consisted of structured multicomponent programs that included exercise and at least one of the following: education, information, health behavior change, and psychological or social support. Usual care interventions generally supervised medical interventions, were the control conditions. Ten studies met reviewers’ eligibility criteria. In a meta-analysis of 5 studies reporting all-cause mortality (an unadjusted outcome), there was a significantly lower risk of death in the group that received cardiac rehabilitation (odds ratio, 0.25; 95% CI, 0.16 to 0.40). Three studies that reported an adjusted analysis of all-cause mortality also found a significant benefit from cardiac rehabilitation (odds ratio=0.47; 95% CI, 0.38 to 0.59). Similarly, a meta-analysis of 3 studies reporting cardiac-related mortality (an unadjusted analysis) found a significant benefit from cardiac rehabilitation (odds ratio=0.21; 95% CI, 0.12 to 0.37). Only 1 study reported an adjusted analysis of cardiac-related mortality, so data could not be pooled.

Nilsson et al (2018) investigated the effect of a 12-week cardiac rehabilitation program with a high-intensity interval exercise component using participant VO2peak as a measure of improved exercise capacity. Increased exercise capacity has been shown to improve survival among persons with CHD. The objective of the study was to assess whether this addition to a cardiac rehabilitation program yielded improved long-term results. One hundred thirty-three coronary patients participated in this prospective cohort study and were evaluated at baseline, at the end of the 12-week program, and again at a 15-month follow-up. Additional test
measurements included a cardiopulmonary exercise test, body mass index, blood pressure tests, and a quality of life questionnaire. Of the 133 patients, 86 patients had complete information for the 15-month follow-up. Mean VO2peak improved from a baseline of 31.9 mL/kg/min to 35.9 mL/kg/min (p<0.001) at the end of the 12-week program, and to 36.8 mL/kg/min (CI not reported) at 15-month follow-up. Most of the 86 patients reported maintaining an exercise routine. Study limitations included the small sample size, a relatively low-risk male population at baseline, and lack of information on the qualifying event for cardiac rehabilitation. The authors concluded that the cardiac rehabilitation program intervention potentially fostered consistent and beneficial exercise habits as demonstrated by improved VO2peak.

Section Summary: Outpatient Cardiac Rehabilitation for Heart Disease
Overall, the evidence from RCTs reviewed in well-structured systematic reviews suggests that cardiac rehabilitation is associated with reduced cardiovascular mortality in patients with CHD. Additional RCTs, systematic reviews, and observational studies have evaluated outpatient cardiac rehabilitation in patients with heart failure or in the postintervention setting. An overview of 6 meta-analyses found a statistically significant association between cardiac rehabilitation and all-cause mortality and/or cardiac mortality. The available evidence has limitations, including lack of blinded outcome assessment, but, for the survival-related outcomes of interest, this limitation is less critical.

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

SUMMARY OF EVIDENCE
For individuals who have diagnosed heart disease who receive outpatient cardiac rehabilitation, the evidence includes multiple 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 selected 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 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.

ONGOING AND UNPUBLISHED CLINICAL TRIALS
Some currently unpublished trials that might influence this policy are listed in Table 1.
In 2013, the American College of Cardiology Foundation and the American Heart Association updated 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 HF [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.

### Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02619422</td>
<td>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</td>
<td>509</td>
<td>Feb 2018 (ongoing)</td>
</tr>
<tr>
<td>NCT02762825</td>
<td>Novel Cardiac Rehabilitation in Patients Heart Failure and Preserved Ejection Fraction</td>
<td>66</td>
<td>Sept 2018 (ongoing)</td>
</tr>
<tr>
<td>NCT02795936a</td>
<td>Feasibility of Cardiac Rehabilitation in Patients With Heart Failure at the Moi Teaching and Referral Hospital</td>
<td>101</td>
<td>Jun 2018 (ongoing)</td>
</tr>
<tr>
<td>NCT03385837</td>
<td>Activity Level and Barriers to Participate of Cardiac Rehabilitation in Advanced Heart Failure Patients</td>
<td>50</td>
<td>Dec 2018 (ongoing)</td>
</tr>
<tr>
<td>NCT02984449</td>
<td>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)</td>
<td>350</td>
<td>Aug 2025 (ongoing)</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01822769</td>
<td>Cardiopulmonary Rehabilitation for Adolescents and Adults With Congenital Heart Disease</td>
<td>28</td>
<td>Dec 2017 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

**SUPPLEMENTAL INFORMATION**

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

**American College of Cardiology Foundation and the American Heart Association**

In 2013, the American College of Cardiology Foundation and the American Heart Association updated 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 HF [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.¹⁷ 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.²⁰

American Heart Association et al
In 2007, the American Heart Association and the American Association of Cardiovascular and Pulmonary Rehabilitation issued an updated consensus statement on the core components of cardiac rehabilitation programs.¹⁸ 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.

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

Government Regulations
National:
Medicare Benefit Policy Manual – Chapter 32, Section 140.1 – Cardiac Rehabilitation Program Services Furnished On or Before December 31, 2009, (Rev. 1882, Issued: 12-21-09; Effective Date: 01-01-10; Implementation Date: 01-04-10)
Medicare covers cardiac rehabilitation exercise programs for patients who meet the following criteria:
- Have a documented diagnosis of acute myocardial infarction within the preceding 12 months; or
- Have had coronary bypass surgery; or
- Have stable angina pectoris; or
- Have had heart valve repair/replacement; or
- Have had percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; or
- Have had a heart or heart-lung transplant

Effective for dates of services on or after March 22, 2006, services provided in connection with a cardiac rehabilitation exercise program may be considered reasonable and necessary for up to 36 sessions. Patients generally receive 2 to 3 sessions per week for 12 to 18 weeks. The contractor has discretion to cover cardiac rehabilitation services beyond 18 weeks. Coverage must not exceed a total of 72 sessions for 36 weeks.
Cardiac rehabilitation programs shall be performed incident to physician’s services in outpatient hospitals, or outpatient settings such as clinics or offices. Follow the policies for services incident to the services of a physician as they apply in each setting. For example, see Pub. 100-02, Chapter 6, §2.4.1, and Pub. 100-02, Chapter 15, §60.1. (Refer to Publication 100-03, §20.10 for further coverage guidelines.)

140.1.1 - Coding Requirements for Cardiac Rehabilitation Services Furnished On or Before Dec. 31, 2009

(Rev. 1882, Issued: 12-21-09; Effective Date: 01-01-10; Implementation Date: 01-04-10)
The following are the applicable HCPCS codes:
93797 - Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session); and 93798 - Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session).

Effective for dates of service on or after January 1, 2008 and before January 1, 2010, providers and practitioners may report more than one unit of CPT code 93797 or 97398 for a date of service if more than one cardiac rehabilitation session lasting at least 1 hour each is provided on the same day. In order to report more than one session for a given date of service, each session must last a minimum of 60 minutes. For example, if the cardiac rehabilitation services provided on a given day total 1 hour and 50 minutes, then only one session should be billed to report the cardiac rehabilitation services provided on that day.

Medicare Benefit Policy Manual – Chapter 32, Section 140.2 – Cardiac Rehabilitation Program Services Furnished On or After January 1, 2010
(Rev. 1882, Issued: 12-21-09; Effective Date: 01-01-10; Implementation Date: 01-04-10)
As specified at 42 CFR 410.49, Medicare covers cardiac rehabilitation items and services for patients who have experienced one or more of the following:
• An acute myocardial infarction within the preceding 12 months; or
• A coronary artery bypass surgery; or
• Current stable angina pectoris; or
• Heart valve repair or replacement; or
• Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; or
• A heart or heart-lung transplant.

Cardiac rehabilitation programs must include the following components:
• 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.

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. This provision is satisfied if the physician meets the requirements for the direct supervision of physician’s office services as specified at 42 CFR 410.26 and for hospital outpatient therapeutic services as specified at 42 CFR 410.27.
As specified at 42 CFR 410.49(f)(1), cardiac 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 for an additional 36 sessions over an extended period of time if approved by the Medicare contractor.

National Coverage Determination (NCD) for Cardiac Rehabilitation Programs for Chronic Heart Failure (20.10.1) Effective Date of this Version 2/18/2014, Implementation Date 8/18/2014

A. General
As per sections 1861(s)(2)(CC) and 1861(eee)(1) of the Social Security Act, items and services furnished under a Cardiac Rehabilitation (CR) program may be covered under Medicare Part B. Among other things, Medicare regulations at 42CFR410.49 define key terms, address the components of a CR program, establish the standards for physician supervision, and limit the maximum number of program sessions that may be furnished. The regulations also describe the cardiac conditions that would enable a beneficiary to obtain CR services. Effective for dates of service on and after January 1, 2010, coverage is permitted for beneficiaries who have experienced one or more of the following:
- Acute myocardial infarction within the preceding 12 months
- Coronary artery bypasses surgery
- Current stable angina pectoris
- Heart valve repair or replacement
- Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting
- A heart or heart-lung transplant

The Centers for Medicare & Medicaid Services (CMS) may add “other cardiac conditions as specified through a national coverage determination” (See 42 CFR §410.49(b)(1)(vii).

Indications and Limitations of Coverage
B. Nationally Covered Indications
Effective for dates of service on and after February 18, 2014, CMS has determined that the evidence is sufficient to expand coverage for cardiac rehabilitation services under 42 CFR §410.49(b)(1)(vii) to beneficiaries with 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 six weeks. Stable patients are defined as patients who have not had recent (≤ 6 weeks) or planned (≤ 6 months) major cardiovascular hospitalizations or procedures. (See section A above for other indications covered under 42 CFR §410.49(b)(1)(vii).

C. Nationally Non-Covered Indications
Any cardiac indication not specifically identified in 42 CFR §410.49(b)(1)(vii) or identified as covered in this NCD or any other NCD in relation to cardiac rehabilitation services is considered non-covered.

Local:
There is no local coverage determination.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicaid Services [CMS, formerly HCFA] are updated)
Related Policies

Intensive Cardiac Rehabilitation
Pulmonary Rehabilitation

References


The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 4/8/19, the date the research was completed.
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<th>Comments</th>
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Next Review Date: 2nd Qtr, 2020
I. Coverage Determination:

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<td>BCN65 (Medicare Complementary)</td>
<td>Coinsurance covered if primary Medicare covers the service.</td>
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II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member’s certificate and is not guaranteed. Please consult the individual member’s certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member’s PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.