Title: Cardiac Rehabilitation, Outpatient

Description/Background

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 2020 update on heart disease and stroke statistics from the American Heart Association, it was estimated that 605,000 Americans have a new coronary attack (first hospitalized myocardial infarction or coronary heart disease death) and 200,000 have a recurrent attack annually.¹ 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 United States annually.² 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.

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.”³ Since the release of the U.S. Public Health Service guidelines, other societies, including the American Heart
Association (2005)\textsuperscript{4} and the Heart Failure Society of America (2010)\textsuperscript{5} have developed guidelines about the role of cardiac rehabilitation in patient care.

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

**Medical Policy Statement**

Short-term outpatient Phase II cardiac rehabilitation is established as safe and effective and is an accepted standard therapy in patients 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”)

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**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*

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**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 1 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.

OUTPATIENT CARDIAC REHABILITATION FOR HEART DISEASE

Clinical Context and Therapy Purpose
The purpose of cardiac rehabilitation in patients who have heart disease is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of cardiac rehabilitation in patients who have heart disease improve net health outcomes?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with diagnosed heart disease.

Interventions
The treatment being considered is cardiac rehabilitation. Cardiac rehabilitation includes long-term programs that include medical evaluation, prescribed exercise, modification to reduce cardiac risks, education, and counseling.

Cardiac rehabilitation is administered by a cardiac rehabilitation specialist on an outpatient clinical basis. Some aspects of cardiac rehabilitation, such as exercise and nutrition changes, are performed by patients at home.

Comparators
The comparator of interest is standard management without cardiac rehabilitation. The following practices are currently being used to manage heart disease: medication, surgery, and medical devices.

Standard management of heart disease is administered by cardiologists in an outpatient clinical setting. Surgery for heart disease is performed by a cardiac surgeon in a tertiary care setting.

Outcomes
The general outcomes of interest are overall survival (OS), disease-specific survival, symptoms, and morbid events.

Once diagnosed with heart disease, a patient will require lifelong monitoring by a cardiologist.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews
Oldridge (2012) identified 6 independent meta-analyses published since 2000 that reported outcomes from 71 RCTs (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 cardiovascular 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 Cochrane reviews. One included patients with coronary heart disease (CHD)7 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 myocardial infarction, CABG, or percutaneous coronary intervention, or with angina pectoris or coronary artery disease. The updated review included 63 RCTs (N=14486 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 versus 375/3619 for control subjects; relative risk [RR], 0.74; 95% confidence interval [CI], 0.64 to 0.86). Rates of myocardial infarction, CABG, and percutaneous coronary intervention were not significantly associated with receiving cardiac rehabilitation.

Long et al (2019) reported a Cochrane Review of studies assessing cardiac rehabilitation in patients with heart failure. A total of 44 RCTs were evaluated; 11 of which were new trials, for the effects of exercise-based cardiac rehabilitation on adults with heart failure (5783 total participants).10 A single trial, Exercise Based Cardiac Rehabilitation for Adults With Heart Failure (HF-ACTION) contributed almost half of the patients (with results reported in 18 publications); most other studies were small and single-center. All studies had 6 months or longer follow-up and did not include a formal exercise training intervention as a comparator. The primary outcomes reported were mortality, hospital admission, and health-related quality of life (HRQoL). The overall risk of bias was assessed as being low or unclear, and results
were downgraded using the GRADE tool for all outcomes except 1. Results showed that cardiac rehabilitation had little effect on all-cause mortality over ≤1 year of follow-up (27 trials, 2596 participants: cardiac rehabilitation 5.1% versus control 5.8%; low-quality evidence). However, cardiac rehabilitation may make a difference in the long-term (>1 year of follow-up; 6 trials, 2845 participants: cardiac rehabilitation 17.2% versus control 19.6%; high-quality evidence). Mortality related to heart failure was not consistently reported in the studies. Chances of avoiding hospital admission for any cause within 12 months of follow-up were better with cardiac rehabilitation (21 trials, 2182 participants: cardiac rehabilitation 16.5% versus control 23.7%; moderate-quality evidence). Cardiac rehabilitation may also reduce short-term heart failure-related hospital admission (14 trials, 1114 participants: cardiac rehabilitation 7.1% versus control 11.1%; RR 0.59, 95% CI, 0.42 to 0.84; \( p = .0003 \)), but the evidence was rated low quality. HRQoL was reported by 29 trials, most of which used the Minnesota Living With Heart Failure questionnaire; however, other tools were also used among the 29 trials that reported validated HRQoL measures. For exercise-based cardiac rehabilitation, no trials reported lower HRQoL scores with cardiac rehabilitation than with control, and all but 1 reported on results at ≥6 months follow-up. The pooled results from all measures used showed a clinically important improvement (a 5-point difference on the Minnesota Living With Heart Failure with exercise at up to 12 months’ follow-up, but the evidence was of very low quality. Compared with the 2014 review, this version included more women, older patients, and participants with heart failure with preserved ejection fraction in recent trials, and with more trials of cardiac rehabilitation in a home-based setting, this version may be more valid and applicable.

Table 1. Systematic Review 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 et al (2010)</td>
<td>1995-2008</td>
<td>29</td>
<td>All adults with chronic systolic HF</td>
<td>3,647 (20-2,331)</td>
<td>RCT</td>
</tr>
<tr>
<td>Oldridge (2012)</td>
<td>2000-2011</td>
<td>71</td>
<td>Patients with MI, CHD, angina, PCI, and/or CABG</td>
<td>13,824 (6,111-10,794)</td>
<td>RCT</td>
</tr>
<tr>
<td>Anderson et al (2016)</td>
<td>1975-2014</td>
<td>63</td>
<td>Patients with MI, angina pectoris, CAD, or who underwent CAGB or PCI</td>
<td>14,486 (25-3,184)</td>
<td>RCT</td>
</tr>
</tbody>
</table>

CABG: coronary artery bypass graft; CAD: coronary artery disease; CHD: coronary heart disease; HF: heart failure; MI: myocardial infarction; PCI: percutaneous coronary intervention; RCT: randomized controlled trial.

Table 2. Systematic Review Results

<table>
<thead>
<tr>
<th>Study</th>
<th>All-Cause Mortality</th>
<th>Cardiovascular Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davies et al (2010)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difference in pooled mortality, fixed-effect RR</td>
<td>1.02</td>
<td>NR</td>
</tr>
<tr>
<td>95% CI</td>
<td>0.70-1.51</td>
<td>NR</td>
</tr>
<tr>
<td>p-value</td>
<td>0.90</td>
<td>NR</td>
</tr>
<tr>
<td>Oldridge (2012)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduction, mean %</td>
<td>18.50</td>
<td>29.4</td>
</tr>
<tr>
<td>p-value</td>
<td>&lt;0.05</td>
<td>NR</td>
</tr>
<tr>
<td>Range, %</td>
<td>NR</td>
<td>20-43</td>
</tr>
</tbody>
</table>
Randomized Controlled Trials

Findings of a large, multicenter RCT from the United Kingdom, which evaluated the effectiveness of cardiac rehabilitation in a “real-life” setting were published by West et al (2012). 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 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 (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 myocardial infarction, 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 United Kingdom. Finally, these results might in part reflect the degree to which clinically-based cardiac rehabilitation programs in the United Kingdom differ from the treatment protocols used in RCTs 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. 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 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. The primary outcome for assessing change in exercise capacity was percentage change in peak oxygen uptake (mL/kg per minute) from baseline to end of exercise training (16-week follow-up). Data on testing from 48 patients (24 reduced ejection

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<table>
<thead>
<tr>
<th>Study</th>
<th>Design/Participants</th>
<th>RR</th>
<th>95% CI</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anderson et al (2016)</td>
<td>47 studies; N=12,455 participants</td>
<td>0.96</td>
<td>0.88-1.04</td>
<td></td>
</tr>
<tr>
<td>Long et al (2019)</td>
<td>2,845 participants, 6 studies</td>
<td>0.88</td>
<td>NR</td>
<td>(studies did not consistently report deaths due to heart failure)</td>
</tr>
</tbody>
</table>

CI: confidence interval; NR: not reported; RR: relative risk
fraction, 24 heart failure with preserved ejection fraction) were assessed. Heart failure with preserved ejection fraction patients experienced greater improvement in exercise training patients (18.7%) than reduced ejection fraction patients (-0.3%; p<0.001) as measured by peak oxygen uptake. 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 heart failure with preserved ejections fraction patients.

Opotowsky et al (2018) compared cardiac rehabilitation to the standard of care in 28 subjects (mean age: 41.1 years) with moderate to severe congenital heart disease. Cardiac rehabilitation was associated with a significant increase in peak oxygen consumption with no associated adverse events. There was also a nonsignificant improvement in peak work rate with cardiac rehabilitation as compared to standard of care (p=0.16) and a significant improvement in self-assessment of overall health (p<0.04). However, the study was limited by its small sample size and short-term follow-up.

Snoek et al (2020) evaluated 6 months of home-based mobile guided cardiac rehabilitation versus standard of care in 179 elderly subjects (mean age: 72 years) with a recent diagnosis of cardiovascular disease. The primary outcome measure was peak oxygen uptake after 6 months. Results revealed that changes in peak oxygen uptake were greater in the cardiac rehabilitation group as compared to the control at both 6 and 12 months. The overall incidence of adverse events was low and did not differ between groups. A limitation of the study was that the authors used home-based mobile guided cardiac rehabilitation as an alternative to exercise-based cardiac rehabilitation and not for comprehensive cardiac rehabilitation, because the authors did not include all core components of cardiac rehabilitation in their intervention. Tables 2 and 3 provide a summary of key RCT characteristics and results.

**Table 3. Summary of Key Randomized Controlled Trial Characteristics**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>West et al (2012); RAMIT</td>
<td>United Kingdom</td>
<td>14</td>
<td>1997-2000</td>
<td>Patients diagnosed with acute MI (N=1813)</td>
<td>Cardiac rehabilitation (n=903) Control (n=910)</td>
</tr>
<tr>
<td>Pandey et al (2017)</td>
<td>U.S.</td>
<td>1</td>
<td>NR</td>
<td>Patients aged ≥ 65 with HFrEF (n=24) or HFpEF (n=24) (N=48)</td>
<td>16-wk supervised moderate endurance exercise training (n=48) HRrEF (n=24) vs. HFpEF (n=24)</td>
</tr>
<tr>
<td>Opotowsky et al (2018)</td>
<td>U.S.</td>
<td>1</td>
<td>NR</td>
<td>Patients aged ≥ 16 with moderate to severe congenital heart disease (N=28)</td>
<td>12-wk cardiac rehabilitation (n=13) Standard of care (n=15)</td>
</tr>
<tr>
<td>Snoek et al (2020)</td>
<td>European Countries</td>
<td>6</td>
<td>2015-2018</td>
<td>Patients aged ≥ 65 with a recent diagnosis of acute coronary syndrome, coronary revascularization, surgical or percutaneous</td>
<td>6-month mobile cardiac rehabilitation (n=89) Standard of care (n=90)</td>
</tr>
</tbody>
</table>
HF: heart failure; HFrEF: HF with reduced ejection fraction; HFrEF: HF with reduced ejection fraction; MI: myocardial infarction; NR: not reported; RCT: randomized controlled trial; RAMIT: Rehabilitation After Myocardial Infarction Trial.

Table 4. Summary of Key Randomized Controlled Trial Results

<table>
<thead>
<tr>
<th>Study</th>
<th>2-yr Mortality</th>
<th>Readmission to Hospital for Any Cardiac Condition at 1 y</th>
<th>Training-Related Improvement in Vo2 peak Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>West et al (2012); RAMIT$^{11}$</td>
<td>N=1813 participants</td>
<td>N=1813 participants</td>
<td>NR</td>
</tr>
<tr>
<td>CR</td>
<td>82 patients</td>
<td>222 (25%)</td>
<td>NR</td>
</tr>
<tr>
<td>Control</td>
<td>84 patients</td>
<td>239 (26%)</td>
<td>NR</td>
</tr>
<tr>
<td>RR</td>
<td>0.98</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>95% CI</td>
<td>0.74-1.30</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Pandey et al (2017)$^{13}$</td>
<td>NR</td>
<td>NR</td>
<td>N=48 participants</td>
</tr>
<tr>
<td>HFrEF</td>
<td>NR</td>
<td>NR</td>
<td>18.7+/−17.6</td>
</tr>
<tr>
<td>HFrEF</td>
<td>NR</td>
<td>NR</td>
<td>−0.3+/−15.4</td>
</tr>
<tr>
<td>p-value</td>
<td>NR</td>
<td>NR</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Opotowsky et al (2018)$^{15}$</td>
<td>NR</td>
<td>NT</td>
<td>+2.2 mL/kg/min (compared to standard of care)</td>
</tr>
<tr>
<td>95% CI; p value</td>
<td>NR</td>
<td>NR</td>
<td>0.7 to 3.7; p=0.002</td>
</tr>
<tr>
<td>Snoek et al (2020)$^{16}$</td>
<td>NR</td>
<td>NR</td>
<td>At 6 months: 1.6 [0.9 to 2.4] mL/kg/min At 12 months: 1.2 [0.4 to 2.0] mL/kg/min</td>
</tr>
<tr>
<td>Standard of care</td>
<td>NR</td>
<td>NR</td>
<td>At 6 months: 0.2 [-0.4 to 0.8] mL/kg/min At 12 months: 0.1 [-0.5 to 0.7] mL/kg/min</td>
</tr>
</tbody>
</table>

CI: confidence interval; CR: cardiac rehabilitation; HF: heart failure; HFrEF: HF with preserved ejection fraction; HFrEF: HF with reduced ejection fraction; NR: not reported; RCT: randomized controlled trial; RR: relative risk; Vo2peak: peak ox; RAMIT: Rehabilitation After Myocardial Infarction Trial.

The purpose of the limitations tables (Tables 5 and 6) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of the evidence supporting the position statement.

Table 5. Study Relevance Limitations

<table>
<thead>
<tr>
<th>Study</th>
<th>Population$^a$</th>
<th>Intervention$^b$</th>
<th>Comparator$^c$</th>
<th>Outcomes$^d$</th>
<th>Follow-Up$^e$</th>
</tr>
</thead>
<tbody>
<tr>
<td>West et al (2012); RAMIT$^{11}$.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.2. Trial was closed prematurely</td>
</tr>
<tr>
<td>Pandey et al (2017)$^{13}$.</td>
<td></td>
<td></td>
<td>2. No comparator used</td>
<td></td>
<td>1.2. Only 16 wks follow-up</td>
</tr>
</tbody>
</table>
Opotowsky et al (2018)\textsuperscript{15}  &  &  & 1. Key health outcomes such as mortality or readmission not addressed  & 1,2. Only 12 wks follow-up  
Snoek et Al (2020)\textsuperscript{16}  & 2. Intervention was an alternative for exercise-based cardiac rehabilitation and not for comprehensive cardiac rehabilitation; authors did not include all core components of cardiac rehabilitation in the intervention  & 1. Key health outcomes such as mortality or readmission not addressed  

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

a 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.
b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.
c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified;
e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

**Table 6. Study Design and Conduct Limitations**

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation\textsuperscript{a}</th>
<th>Blinding\textsuperscript{b}</th>
<th>Selective Reporting\textsuperscript{c}</th>
<th>Follow-Up\textsuperscript{d}</th>
<th>Power\textsuperscript{e}</th>
<th>Statistical\textsuperscript{f}</th>
</tr>
</thead>
<tbody>
<tr>
<td>West et al (2012); RAMIT\textsuperscript{,11}</td>
<td>3. Allocation concealment unclear</td>
<td>1,2. Not blinded</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pandey et al (2017)\textsuperscript{,13}</td>
<td>1. Participants not randomly allocated</td>
<td>1,2. Not blinded</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opotowsky et al (2018)\textsuperscript{15}</td>
<td></td>
<td>1,2. Not blinded</td>
<td></td>
<td>1. Power calculations Not reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Snoek et al (2020)\textsuperscript{16}</td>
<td>2. Not blinded to outcome assessment</td>
<td></td>
<td>3. Not powered to detect a difference in hard outcomes or more rare adverse events</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Com RAMIT: Rehabilitation After Myocardial Infarction Trial.

**Observational Studies**

Sumner et al (2017) published a systematic review of controlled observational studies evaluating cardiac rehabilitation in patients diagnosed with acute myocardial infarction.\textsuperscript{17} Cardiac rehabilitation interventions consisted of structured multicomponent programs that included exercise and at least 1 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 peak oxygen uptake as a measure of improved exercise capacity. Increased exercise capacity has been shown to improve survival among persons with coronary heart disease. 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 peak oxygen uptake 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 peak oxygen uptake.

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 coronary heart disease. 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

Clinical Context and Therapy Purpose
The purpose of repeat cardiac rehabilitation in patients who have heart disease without a second event is to provide a treatment option that is an alternative to or an improvement on existing therapies.
The question addressed in this evidence review is: Does the use of repeat cardiac rehabilitation in patients who have heart disease without a second event improve net health outcomes?

The following PICO was used to select literature to inform this review.

**Populations**
The relevant population of interest is patients with diagnosed heart disease who have had cardiac rehabilitation before but who have not had a second cardiac event.

**Interventions**
The treatment being considered is repeat cardiac rehabilitation. Cardiac rehabilitation includes long-term programs that include medical evaluation, prescribed exercise, modification to reduce cardiac risks, education, and counseling.

Cardiac rehabilitation is administered by a cardiac rehabilitation specialist on an outpatient clinical basis. Some aspects of cardiac rehabilitation, such as exercise and nutrition changes, are performed by patients at home.

**Comparators**
The comparator of interest is standard management with a single course of cardiac rehabilitation. Cardiac rehabilitation includes long-term programs that include medical evaluation, prescribed exercise, modification to reduce cardiac risks, education, and counseling.

Cardiac rehabilitation is administered by a cardiac rehabilitation specialist on an outpatient clinical basis. Some aspects of cardiac rehabilitation, such as exercise and nutrition changes, are performed by patients at home.

**Outcomes**
The general outcomes of interest are OS, disease-specific survival, symptoms, and morbid events.

Once diagnosed with heart disease, a patient will require lifelong monitoring by a cardiologist.

**Study Selection Criteria**
Methodologically credible studies were selected using the principles described in the first indication.

**REVIEW OF EVIDENCE**

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 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 that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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.

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 their joint guidelines on the management of heart failure. These guidelines included the following Class IIA recommendation on cardiac rehabilitation (level of evidence: B): “Cardiac rehabilitation can be useful in clinically stable patients with heart failure to improve functional capacity, exercise duration, health-related quality of life, and mortality.” The 2017 focused update of the guideline did not include additional information on cardiac rehabilitation.

American College of Physicians
In 2012, the American College of Physicians and 6 other cardiology associations published joint guidelines on the management of stable ischemic heart disease. The guidelines included the following statement on cardiac rehabilitation: “Medically supervised exercise programs, (cardiac rehabilitation) and physician-directed, home-based programs are recommended for at-risk patients at first diagnosis.” The 2014 update to the guideline did not include additional information on cardiac rehabilitation.

American Heart Association et al
In 2007, the American Heart Association and the American Association of Cardiovascular and Pulmonary Rehabilitation issued an updated consensus statement on the core components of
cardiac rehabilitation programs. The core components included patient assessment before beginning the program, nutritional counseling, weight management, blood pressure management, lipid management, diabetes management, tobacco cessation, psychosocial management, physical activity counseling, and exercise training. Programs that only offered supervised exercise training were not considered cardiac rehabilitation. The guidelines specified the assessment, interventions, and expected outcomes for each of the core components. For example, symptom-limited exercise testing before exercise training was strongly recommended. The guidelines did not specify the optimal overall length of programs or number or duration of sessions.

In 2019, the American Heart Association, with the American Association of Cardiovascular and Pulmonary Rehabilitation and the American College of Cardiology, released a scientific statement on home-based cardiac rehabilitation. They make the following suggestions for healthcare providers:

- Recommend center-based cardiac rehabilitation (CBCR) to all eligible patients.
- As an alternative, recommend home-based cardiac rehabilitation (HBCR) to clinically stable low- and moderate-risk patients who cannot attend CBCR.
- Design and test HBCR “using effective processes of care for CVD secondary prevention.”
- For healthcare organizations, develop and support the following:
  - Maximization of CR referrals
  - High-quality CBCR and HBCR programs “using evidence-based standards and guidelines, strategies to maximize patient adherence both in the shorter and longer-term, and outcome tracking methods to help promote continuous quality improvement.”
  - “Testing and implementation of evidence-based hybrid approached to CR” that are optimized for each patient and that “promote long-term adherence and favorable behavior change.”
- For CR professionals, “work with other healthcare professionals and policymakers to implement additional research and...expand the evidence base for HBCR.”

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

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 7.

Table 7. Summary of Key Trials

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<td>Novel Cardiac Rehabilitation in Patients With Heart Failure and Preserved Ejection Fraction</td>
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<td>Effectiveness of a Cardiac Rehabilitation Program in Patients With Heart Failure</td>
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<td>Dec 2021</td>
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<tr>
<td>NCT03218891</td>
<td>Cardiac Rehabilitation in Patients With Refractory Angina</td>
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<td>Mar 2023</td>
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Government Regulations
National:
Medicare Benefit Policy Manual, Chapter 15, Section 232 Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished on or after January 1, 2010(Rev. 10573; Issued: 03-24-2021; Effective: 01-01-2010; Implementation: 04-26-2021)

Cardiac rehabilitation (CR) means a physician-supervised program that furnishes physician prescribed exercise; cardiac risk factor modification, including education, counseling, and behavioral intervention; psychosocial assessment; and outcomes assessment. Intensive cardiac rehabilitation (ICR) program means a physician-supervised program that furnishes CR and has shown, in peer-reviewed published research, that it improves patients’ cardiovascular disease through specific outcome measurements described in 42 CFR 410.49(c). Effective January 1, 2010, Medicare Part B pays for CR/ICR programs and related items/services if specific criteria are met by the Medicare beneficiary, the CR/ICR program itself, the setting in which it is administered, and the physician administering the program, as outlined below.

Covered beneficiary cardiac and intensive cardiac rehabilitation services:
Medicare part B covers CR and ICR program services for beneficiaries who have experienced one or more of the following:
- An acute myocardial infarction within the preceding 12 months;
- A coronary artery bypass surgery;
- Current stable angina pectoris;
- Heart valve repair or replacement;
- Percutaneous transluminal coronary angioplasty or coronary stenting;
- A heart or heart-lung transplant.
- Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal medical therapy for at least 6 weeks, on or after February 18, 2014 for CR and on or after February 9, 2018 for ICR; or
• Other cardiac conditions as specified through a national coverage determination (NCD). The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

CR and ICR programs must include all of the following:

Physician-prescribed exercise. Physician-prescribed exercise means aerobic exercise combined with other types of exercise (that is, strengthening, stretching) as determined to be appropriate for individual patients by a physician each day CR/ICR items and services are furnished.

Cardiac risk factor modification. Cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to the patients’ individual needs.

Psychosocial assessment. Psychosocial assessment means an evaluation of an individual’s mental and emotional functioning as it relates to the individual’s rehabilitation which includes an assessment of those aspects of an individual’s family and home situation that affects the individual’s rehabilitation treatment, and, psychosocial evaluation of the individual’s response to and rate of progress under the treatment plan.

Outcomes assessment. Outcomes assessment means an evaluation of progress as it relates to the individual’s rehabilitation which includes all of the following: (i) Minimally, assessments from the commencement and conclusion of CR and ICR, based on patient-centered outcomes which must be measured by the physician immediately at the beginning of the program and at the end of the program. (ii) Objective clinical measures of exercise performance and self-reported measures of exertion and behavior.

Individualized treatment plan. Individualized treatment plan means a written plan tailored to each individual patient that includes all of the following: (i) A description of the individual’s diagnosis. (ii) The type, amount, frequency, and duration of the items and services furnished under the plan. (iii) The goals set for the individual under the plan. The individualized treatment plan detailing how components are utilized for each patient, must be established, reviewed, and signed by a physician every 30 days.

As specified at 42 CFR 410.49(f)(1), CR 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 under section 1862(a)(1)(A) of the Act. As specified at 42 CFR 410.49(f)(2), ICR program sessions are limited to 72 1-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks.

CR and ICR Settings:
CR and ICR 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 times when items and services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision for physician office services as specified at 42 CFR 410.26, and for hospital outpatient services as specified at 42 CFR 410.27.
As specified at 42 CFR 410.49, Medicare covers cardiac rehabilitation program services for beneficiaries 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.

Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent 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, on or after February 18, 2014; or

- Other cardiac conditions as specified through a national coverage determination (NCD).

Cardiac rehabilitation programs must include all of 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. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

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 for physician 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 on this topic.

*(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 and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*
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 5/3/21, the date the research was completed.
### Joint BCBSM/BCN Medical Policy History

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Removed phase I from exclusions  
Added “documented within the last 12 months” to indications listed under inclusions |
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| 9/1/20                | 6/16/20              |                   | Routine maintenance |
| 9/1/21                | 6/15/21              |                   | Routine maintenance. Added ref 1,15, 16 |

Next Review Date: 2nd Qtr, 2022
BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: CARDIAC REHABILITATION

I. Coverage Determination:

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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.