Policy Statement

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

- Acute myocardial infarction (heart attack) within the preceding 12 months
- Compensated heart failure
- Coronary artery bypass graft surgery
- Current stable angina pectoris
- Heart or heart-lung transplantation
- Heart valve surgery
- Percutaneous transluminal coronary angioplasty or coronary stenting

A repeat outpatient cardiac rehabilitation program may be considered medically necessary, based on the above listed criteria, if the patient has another qualifying cardiac event including any of the following:

- Another cardiovascular surgery
- Another coronary vessel intervention procedure (i.e., PTCA or coronary stenting)
- Another documented MI, or extension of initial infarction
- New clinically significant coronary lesions documented by cardiac catheterization
- New evidence of ischemia on an exercise test, including thallium scan

Outpatient cardiac rehabilitation programs are considered not medically necessary for either of the following:

- Phase III cardiac rehabilitation programs, or self-directed, self-controlled/monitored exercise programs (see Policy Guidelines)
- Phase IV cardiac rehabilitation programs or maintenance therapy that may be safely carried out without medical supervision (see Policy Guidelines)

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

Policy Guidelines

The following components must be included in cardiac rehabilitation programs:

- Cardiac risk factor modification
- Individualized treatment plan detailing how each of the above components are utilized
- Outcomes assessment
- Physician-prescribed exercise each day cardiac rehabilitation services are provided
- Psychosocial assessment

A cardiac rehabilitation exercise program is eligible for coverage for 3 sessions per week up to a 12-week period (36 sessions). Programs should start within 90 days of the cardiac event and be completed within 6 months of the cardiac event.

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

Physical and/or occupational therapy are not medically necessary in conjunction with cardiac rehabilitation unless performed for an unrelated diagnosis.
Note: This policy does not address programs considered to be “intensive cardiac rehabilitation programs,” such as the Dean Ornish Program for Reversing Heart Disease and the Pritikin Program.

Description

Cardiac rehabilitation refers to comprehensive medically supervised programs in the outpatient setting that aim to improve the function of patients with heart disease and prevent future cardiac events. National organizations have specified core components to be included in cardiac rehabilitation programs.

Related Policies

- Lifestyle Modification Program for Reversing Heart Disease

Benefit Application

Benefit determinations should be based on all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

- N/A

Rationale

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 infarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the psychosocial and vocational status of selected patients.” The 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 multidisciplinary 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) and the Heart Failure Society of America (2010) have developed guidelines on the role of cardiac rehabilitation in patient care.

**Literature Review**

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 a 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=13,824 patients) following cardiac rehabilitation interventions. 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. Also, 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 CHD and the other focused on patients with systolic heart failure. Both addressed exercise-based cardiac rehabilitation programs (exercise alone or as part of a comprehensive program). Anderson et al (2016) updated a 2011 Cochrane review addressing exercise-based cardiac rehabilitation for individuals with CHD. 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.9 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 I 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 the 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 the differences in 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 the 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)7</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)5</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>Taylor (2014)9</td>
<td>1995-2012</td>
<td>33</td>
<td>Patients with HF</td>
<td>4740</td>
<td>RCT</td>
</tr>
<tr>
<td>Anderson (2016)6</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.

Table 2. SR & MA Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Increase in VO2 Max</th>
<th>Reduction in All-Cause Mortality</th>
<th>Cardiovascular Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Davies (2010)7</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)5</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)9</td>
<td>RR</td>
<td>0.93</td>
<td>0.69-1.27</td>
</tr>
<tr>
<td>95% CI</td>
<td></td>
<td>0.59</td>
<td></td>
</tr>
<tr>
<td>Anderson (2016)6</td>
<td>RR</td>
<td>0.96</td>
<td>0.74</td>
</tr>
<tr>
<td>95% CI</td>
<td>0.88-1.04</td>
<td>0.64-0.86</td>
<td></td>
</tr>
</tbody>
</table>

RR: risk ratio; CI: confidence interval.
Randomized Controlled Trials

Findings of a large, multicenter RCT from the U.K., which evaluated the effectiveness of cardiac rehabilitation in a “real-life” setting, were published by West et al (2012).10 Called the Rehabilitation After Myocardial Infarction Trial (RAMIT), the study included patients from 14 centers with established multifactorial cardiac rehabilitation programs (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% (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 MI, stroke, or revascularization, the RR was 0.96 (95% CI, 0.88 to 1.07). In discussing the study’s negative findings, trialists noted that medical management of heart disease had 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 the 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.11 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 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 might 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.12 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]).13 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 hospitalizations 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>
</tr>
</thead>
<tbody>
<tr>
<td>West (2012); RAMIT</td>
<td>UK</td>
<td>14</td>
<td>1997-2000</td>
<td>Patients diagnosed with acute MI (n=903)</td>
<td>Cardiac rehabilitation (n=903) Control (n=910)</td>
</tr>
<tr>
<td>Pandey (2017)</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>
</tr>
</tbody>
</table>

RCT: randomized controlled trial; MI: myocardial infarction; NR: not reported; HF: heart failure; 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>X 2yr Mortality</th>
<th>Readmissions to Hospital for any Cardio Condition at 1yr</th>
<th>Training Related Improvement in VO2 peak change</th>
</tr>
</thead>
<tbody>
<tr>
<td>West (2012)10</td>
<td>82 patients</td>
<td>222 (25%)</td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>84 patients</td>
<td>239 (26%)</td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td>0.74-1.30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pandey (2017)12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HfEF</td>
<td>18.7+/−17.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HfPEF</td>
<td>−0.3+/−15.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P-value</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RCT: randomized controlled trial; Yr.: year; CR: cardiac rehabilitation; Cardio.: cardiovascular; VO2 peak: 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)10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,2. Trial was closed prematurely</td>
</tr>
<tr>
<td>Pandey (2017)12</td>
<td></td>
<td></td>
<td>2. No comparator used</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.

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 established and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 6. Study Design and Conduct Gaps

<table>
<thead>
<tr>
<th>Study</th>
<th>Allocation</th>
<th>Blinding</th>
<th>Selective Reporting</th>
<th>Follow-Up</th>
<th>Power</th>
<th>Statistical</th>
</tr>
</thead>
<tbody>
<tr>
<td>West (2012)10</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 (2017)12</td>
<td>1. Participants not randomly allocated</td>
<td>1,2. Not blinded</td>
<td></td>
<td></td>
<td></td>
<td></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.

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 noninferiority trials).
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. Comparative treatment effects not calculated.
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.

Intensive Cardiac Rehabilitation for Heart Disease

There is no standard definition of an intensive cardiac rehabilitation program and, thus, specific programs are reviewed individually. Two programs have been evaluated by Centers for Medicare & Medicaid Services, and we describe the published evidence supporting these programs next. The ideal trial design would be an RCT comparing the impact of intensive cardiac rehabilitation with standard cardiac rehabilitation on health outcomes.

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 the effects of the technology on health outcomes.

**Supplemental Information**

**Practice Guidelines and Position Statements**

**American College of Cardiology Foundation et al**
In 2013, the American College of Cardiology Foundation and the American Heart Association updated their joint guidelines on the management of heart failure.2 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.16,

**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.18,

**American Heart Association et al**
In 2007, the American Heart Association and the American Association of Cardiovascular and Pulmonary Rehabilitation issued a consensus statement on the core components of cardiac rehabilitation programs.19, 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.

**Medicare National Coverage**
**Cardiac Rehabilitation**
Medicare has had a national coverage determination for cardiac rehabilitation since 1989. There was a change in Medicare coverage for cardiac rehabilitation in 2010.20, Indications for coverage remained the same; namely, patients who have experienced at least one of the following:
• Acute myocardial infarction within the preceding 12 months
• Coronary artery bypass surgery
• Current stable angina pectoris
• Heart valve repair or replacement
• Percutaneous transluminal coronary angioplasty or coronary stenting
• Heart or heart-lung transplant

As of February 2014, patient eligibility criteria were expanded for cardiac rehabilitation to include patients with the following: “Stable, chronic heart failure, defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks. Stable patients are defined as patients who have not had recent (≤ 6 weeks) or planned (≤ 6 months) major cardiovascular hospitalizations or procedures.”21

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

• Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished
• Cardiac risk factor modification, including education, counseling and behavioral intervention at least once during the program, tailored to patients' individual needs
• Psychosocial assessment
• Outcomes assessment
• An individualized treatment plan detailing how components are utilized for each patient

Also, criteria on the frequency and duration of cardiac rehabilitation services were updated. Beginning in January 2010, the criteria were updated:

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 times items and services are being furnished under the program....

...[C]ardiac rehabilitation program sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks, with the option of an additional 36 sessions over an extended period of time if approved by the Medicare contractor.

Intensive Cardiac Rehabilitation

Beginning in January 2010, Medicare added intensive cardiac rehabilitation as a benefit. Intensive cardiac rehabilitation programs must be approved by Medicare on an individual basis.22

The national coverage determination described intensive cardiac rehabilitation in the following manner:

“Intensive cardiac rehabilitation (ICR) refers to a physician-supervised program that furnishes cardiac rehabilitation services more frequently and often in a more rigorous manner. As required by §1861(eee)(4)(A) of the Social Security Act (the Act), an ICR program must show, in peer-reviewed published research, that it accomplished one or more of the following for its patients: (1) positively affected the progression of coronary heart disease; (2) reduced the need for coronary bypass surgery; and, (3) reduced the need for percutaneous coronary interventions. The ICR program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in five or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services: (1) low density lipoprotein; (2) triglycerides; (3) body mass index; (4) systolic blood pressure; (5) diastolic blood pressure; and, (6) the need for cholesterol, blood pressure, and diabetes medications. Individual ICR programs must be approved through the national coverage determination process to ensure that they demonstrate these accomplishments.”
Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

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>
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<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>
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<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>
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<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>
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<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>
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<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</td>
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<tr>
<td>NCT01822769</td>
<td>Cardiopulmonary Rehabilitation for Adolescents and Adults with Congenital Heart Disease</td>
<td>28</td>
<td>Dec 2017 (completed)</td>
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</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

References


**Documentation for Clinical Review**

Please provide the following documentation (if/when requested):

- History and physical and/or cardiac consultation notes including:
  - Current disease condition(s) and comorbidity status
  - Current functional, mobility, and psychosocial status
  - Documentation of cardiac event(s) including dates of occurrence
  - Individualized treatment plan (description of the diagnosis, type/amount/frequency and duration of the cardiac rehabilitation services)
  - Surgical procedure(s) and procedure date(s) pertaining to request
  - Type of cardiac rehabilitation program and components requested

**Post Service**

- Daily cardiac rehabilitation treatment records
- Physician measured outcomes assessment (e.g., from the commencement and conclusion of cardiac rehabilitation services)

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

**MN/IE**

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tr>
<td></td>
<td>93015</td>
<td>Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress with supervision, interpretation and report</td>
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<td>CPT®</td>
<td>93016</td>
<td>Cardiovascular stress test using maximal or submaximal treadmill or bicycle exercise, continuous electrocardiographic monitoring, and/or pharmacological stress, supervision only, without interpretation and report</td>
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<td>93797</td>
<td>Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)</td>
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### Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment,
procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.