Medical Policy

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Title: Cardiac Rehabilitation in the Outpatient Setting

Professional
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Current Effective Date: August 18, 2017

Populations	Interventions	Comparators	Outcomes
Individuals: • With diagnosed heart disease	Interventions of interest are: • Outpatient cardiac rehabilitation	Comparators of interest are: • Standard management without cardiac rehabilitation	Relevant outcomes include: • Overall survival • Disease-specific survival • Symptoms • Morbid events
Individuals: • With diagnosed heart disease without a second event	Interventions of interest are: • Repeat outpatient cardiac rehabilitation	Comparators of interest are: • Single course of outpatient cardiac rehabilitation	Relevant outcomes include: • Overall survival • Disease-specific survival • Symptoms • Morbid events

Populations	Interventions	Comparators	Outcomes
Individuals: • With diagnosed heart disease	Interventions of interest are: • Intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease	Comparators of interest are: • Standard outpatient cardiac rehabilitation	Relevant outcomes include: • Overall survival • Disease-specific survival • Symptoms • Morbid events
Individuals: • With diagnosed heart disease	Interventions of interest are: • Intensive cardiac rehabilitation with the Pritikin Program	Comparators of interest are: • Standard outpatient cardiac rehabilitation	Relevant outcomes include: • Overall survival • Disease-specific survival • Symptoms • Morbid events

DESCRIPTION

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

OBJECTIVE

The objective of this policy is to determine whether outpatient cardiac rehabilitation programs improve the health outcomes in patients with heart disease.

BACKGROUND

Heart Disease

Heart disease is the leading cause of mortality in the U.S., causing more than half of all deaths. Coronary artery disease (CAD) is the most common cause of heart disease. 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.[1] Both CAD 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.[2] Given the disease burden of heart disease, preventing secondary cardiac events and treating the symptoms of heart disease and heart failure have received much attention from national organizations.

Cardiac Rehabilitation

In 1995, the U.S. Public Health Service (USPHS) defined cardiac rehabilitation services as, in part, "comprehensive, long-term programs involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling. These programs are designed to limit the physiologic and psychological effects of cardiac illness, reduce the risk for sudden death or reinfarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the psychosocial and vocational status of selected patients." This USPHS guideline recommended cardiac rehabilitation services for patients with coronary heart disease (CHD) and with heart failure, including those awaiting or following cardiac transplantation. A 2010 definition of cardiac rehabilitation by the Cardiac

Rehabilitation Section of the European Association of Cardiovascular Prevention and Rehabilitation is as follows: "Cardiac rehabilitation can be viewed as the clinical application of preventive care by means of a professional multi-disciplinary integrated approach for comprehensive risk reduction and global long-term care of cardiac patients."[3] Since the release of the USPHS guideline, other societies, including the American Heart Association[4] and the Heart Failure Society of America[5] have developed guidelines about the role of cardiac rehabilitation in patient care.

REGULATORY STATUS

Not applicable.

POLICY

A. Outpatient cardiac rehabilitation programs are considered **medically necessary** for patients with a history of the following conditions and procedures:
   1. An acute myocardial infarction (MI) (heart attack) within the preceding 12 months; **OR**
   2. A coronary artery bypass graft (CABG) surgery; **OR**
   3. Current stable angina pectoris; **OR**
   4. Heart valve surgery; **OR**
   5. Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; **OR**
   6. A heart or heart-lung transplant; **OR**
   7. Compensated heart failure.

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

C. Intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease or Pritikin Program is considered **experimental / investigational**.

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

Policy Guidelines

1. Cardiac rehabilitation programs must include the following components:
   a. Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished;
   b. Cardiac risk factor modification;
   c. Psychosocial assessment;
   d. Outcomes assessment; and
   e. An individualized treatment plan detailing how each of the above components are utilized.
2. Cardiac rehabilitation items and services must be furnished in a physician's office or a hospital outpatient setting.

3. 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.
4. Duration of the Program:
   A cardiac rehabilitation exercise program is eligible for BCBSKS members, services provided in connection with an approved cardiac rehabilitation exercise program may be considered reasonable and necessary for up to 18 sessions, usually 3 sessions a week in a single 6-week period. Coverage for continued participation would be allowed only on a case-by-case basis with exit criteria taken into consideration. It is preferable that programs start within 90 days of the cardiac event and be completed within 6 months of the cardiac event.
5. 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.

RATIONALE

The most recent literature review was from through January 6, 2019. The following is a description of the key literature to date.

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=13824 patients) following cardiac rehabilitation interventions.[5,

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[6,] and the other focused on patients with systolic heart failure.[7,] 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.[6,8,] 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 II and III heart failure. The trials had a moderate risk of bias; many earlier studies (particularly pre-2000) had insufficient detail to permit assessment of 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

Study	Dates	Trials	Participants	N..Range.	Design
Davies (2010)[7,]	1990-2002	29	All adults with chronic HF	1126	RCT
Oldridge (2012)[5,]		71	Patients with MI, CHD, angina, PCI, and/or CABG	13,824	RCT
Taylor (2014)[9,]	1995-2012	33	Patients with HF	4740	RCT
Anderson (2016)[6,]	1975-2014	63	Patients with MI, angina pectoris, CAD, or who underwent CABG or PCI	14,486	RCT

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

Study	IncreaseinVO2Max	Reduction in All Cause Mortality	Cardiovascular Mortality
Davies (2010)[7,]	2.16 ml/kg/min		
95% CI	2.82-1.49		
Oldridge (2012)[5,]		18.50%	
P-value		<0.05	
Taylor (2014)[9,]			
RR		0.93	
95% CI		0.69-1.27	
P-value		0.59	
Anderson (2016)[6,]			
RR		0.96	0.74
95% CI		0.88-1.04	0.64-0.86

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 randomized¾903 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 2years (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 (HFpEF) 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 (VO_2peak) (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 HFpEF) were assessed. HFpEF patients experienced greater improvement in exercise training patients (18.7%) than reduced ejection faction patients (-0.3%; $p<0.001$) as measured by VO_2peak. 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 HFpEF patients.

Table 3. Summary of Key RCT Characteristics

StudyTrial	Countries	Sites	Dates	Participants	Interventions	X
					Active	Comparator
West (2012); RAMIT[10,]	UK	14	1997-2000	Patients diagnosed with acute MI	Cardiac rehabilitation (n=903)	Control (n=910)
Pandey (2017)[12,]	US	1	NR	Patients age 65 with either HFrEF (n=24) or HFpEF (n=24)	16-week supervised moderate endurance exercise training	

RCT: randomized controlled trial; MI: myocardial infarction; NR: not reported; HF: heart failure; HFrEF: HF with reduced ejection fraction; HFpEF: HF with preserved ejection fraction.

Table 4. Summary of Key RCT Results

Study	X2yr Mortality	Readmissions to Hospital for any Cardio Condition at 1yr	Training Related Improvement in VO2 peak change
West (2012)[10,]			
CR	82 patients	222 (25%)	
Control	84 patients	239 (26%)	
95% CI	0.74-1.30		
Pandey (2017)[12,]			
HFrEF			18.7+/-17.6
HFpEF			-0.3+/-15.4
P-value			<0.001

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

Table 5. Relevance Gaps

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	FollowUp[e]
West (2012)[10,]					1,2. Trial was closed prematurely
Pandey (2017)[12,]			2. No comparator used		1,2. Only 16 weeks follow-up

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 establish 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

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow Up[d]	Power[e]	Statistical[f]
West (2012)[10,]	3. Allocation concealment unclear	1,2. Not blinded				
Pandey (2017)[12,]	1. Participants not randomly allocated	1,2. Not blinded				

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
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.[14,] 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 VO_2peak as a measure of improved exercise capacity.[15,] 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 VO_2peak 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 VO_2peak.

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.

Ornish Program for Reversing Heart Disease
Ornish et al (1990) conducted an RCT, called the Lifestyle Heart Trial, comparing a version of the Ornish Program for Reversing Heart Disease with usual care. Initial results were reported in 1990, and 5-year results in 1998.[16,17,] Eligibility for the trial included diagnosed coronary artery disease, left ventricular ejection fraction greater than 25%, no MI during the previous 6 weeks, no scheduled for CABG, and not taking lipid-lowering medication. Ninety-four eligible patients were randomized to an intervention group (n=53) or a usual care control group (n=43). Final consenting was done after randomization; 28 (53%) of patients assigned to the intervention group and 20 (43%) assigned to the control group agreed to participate in the trial.

The Lifestyle intervention consisted of recommending a low-fat vegetarian diet and an individualized exercise regimen. Also, patients were taught stress management techniques and were taught to practice them at home for at least an hour a day. Also, twice-weekly group discussions were offered to provide social support. It is not clear how long patients attended these group discussion (ie, the number of weeks or months). As reported by Ornish et al (1990), the mean percentage diameter stenosis decreased from 40% at baseline to 37.8% at 1 year in the intervention group and increased from 42.7% to 46.1% in the control group (p=0.001). The frequency and duration of chest pain did not differ between groups. However, during chest pain episodes, at 1 year, the intervention group reported mean chest pain severity of 1.7 (on a 7-point scale) whereas the mean score in the control group was 2.5 (p<0.001).

Twenty (71%) of 28 patients in the intervention group and 15 (75%) of 20 in the control group completed the 5-year follow-up. The intervention and control groups did not differ significantly in the number of MI events (2 vs 4), CABGs (2 vs 5), or deaths (2 vs 1). However, compared with

the control group, the intervention group had significantly fewer percutaneous transluminal coronary angioplasties (8 vs 14, p<0.050) and cardiac hospitalizations (23 vs 44, p<0.001).

Section Summary: Ornish Program for Reversing Heart Disease
One RCT was identified that evaluated the Ornish Program in patients diagnosed with heart disease, and compared it with usual care. This RCT, which included patients with coronary artery disease but no recent cardiac event, had mixed findings at 1 and 5 years. The trial had a small sample size for a cardiac trial (N=48), and only 35 patients were available for the 5-year follow-up. The Ornish Program is considered by Centers for Medicare & Medicaid Services to be an intensive cardiac rehabilitation program, but the program described in this RCT might meet criteria for standard cardiac rehabilitation. No studies were identified that compared the Ornish Program with any other cardiac rehabilitation program.

Pritikin Program
No RCTs evaluating the Pritikin Program were identified. The published evidence on this program consists of case series, and only one (Barnard et al [1983]) included patients with heart disease.[18,] (Other case series included patients without heart failure, eg, those with high cholesterol levels.) Sixty-four patients with documented coronary artery disease attended a 26-day residential treatment program between 1976 and 1977. During the program, patients were encouraged to walk for 30 to 45 minutes twice a day, learned how to prepare foods consistent with the Pritikin diet, and attended over 60 hours of group education classes. Serum samples were taken at baseline and the end of the program. Patients were called in March 1980 for a follow-up interview and asked to send in serum samples. At the 3- to 4-year follow-up, 12 (19%) of 64 patients had had bypass surgery, and4 patients had died. Fifty (81%) patients provided serum samples at follow-up, and the mean cholesterol level (166 mg/dL) was significantly lower than the baseline value (220 mg/dL). The trial was limited in the lack of a control group, especially a group receiving "standard" outpatient cardiac rehabilitation, and long-term mortality outcomes were not reported.

Section Summary: Pritikin Program
No RCTs have evaluated the Pritikin Program; a single case series in patients with heart disease was identified. Conclusions cannot be drawn from this series on the impact of intensive cardiac rehabilitation with the Pritikin Program compared with standard outpatient cardiac rehabilitation.

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.

For individuals who have diagnosed heart disease who receive intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease, the evidence includes an RCT and uncontrolled studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, and morbid events. No RCTs have compared the Ornish Program with a "standard" cardiac rehabilitation program; an RCT compared it with usual care. The trial included patients with coronary artery disease and no recent cardiac events and had mixed findings at 1 and 5 years. The trial had a small sample size for a cardiac trial (N=48), and only 35 patients were available for the 5-year follow-up. The Ornish Program is considered by the Centers for Medicare & Medicaid Services as an intensive cardiac rehabilitation program, but the program described in the RCT could meet criteria for standard cardiac rehabilitation. No studies were identified comparing the Ornish Program with any other cardiac rehabilitation program. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have diagnosed heart disease who receive intensive cardiac rehabilitation with the Pritikin Program, the evidence includes a case series. Relevant outcomes are overall survival, disease-specific survival, symptoms, and morbid events. Studies are needed that compare the impact of intensive cardiac rehabilitation using the Pritikin Program with standard outpatient cardiac rehabilitation programs. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 published updated guidelines on the management of heart failure.[2] These guidelines include the following Class IIA recommendation related to cardiac rehabilitation (Level of Evidence: B): "Cardiac rehabilitation can be useful in clinically stable patients with HF [heart failure] to improve functional capacity, exercise duration, HRQOL [health-related quality of life], and mortality."

American College of Physicians et al

In 2012, the American College of Physicians, American College of Cardiology Foundation, American Heart Association/American Association for Thoracic Surgery, Preventive Cardiovascular Nurses Association and Society of Thoracic Surgeons published a joint guideline on management of stable ischemic heart disease.[20] The guideline 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.[21]

AHA and American Association of Cardiovascular and Pulmonary Rehabilitation

In 2007, AHA and the American Association of Cardiovascular and Pulmonary Rehabilitation issued a consensus statement on the core components of cardiac rehabilitation programs.[22] 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 offer supervised exercise training are 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 national 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.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this policy are listed in Table 7.

Table 7. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02619422	More Intensive Cardiac Rehabilitation Programs in Less Time (másPORmenos)	509	Feb 2018 (ongoing)
NCT02762825	Novel Cardiac Rehabilitation in Patients Heart Failure and Preserved Ejection Fraction	66	Sep 2018 (ongoing)
NCT02795936[a]	Feasibility of Cardiac Rehabilitation in Patients With Heart Failure at the Moi Teaching and Referral Hospital	101	Jun 2018 (ongoing)
NCT03385837	Activity Level and Barriers to Participate of Cardiac Rehabilitation in Advanced Heart Failure Patients	50	Dec 2018 (ongoing)
NCT02984449	Preventive Heart Rehabilitation to Prevent Complications in Patients Undergoing Elective Open Heart Surgery (Heart-ROCQ)	350	Aug 2025
Unpublished			
NCT01822769	Cardiopulmonary Rehabilitation for Adolescents and Adults With Congenital Heart Disease	28	Dec 2017 (completed)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

BENEFIT APPLICATION

Cardiac rehabilitation must be performed in a facility approved by Blue Cross and Blue Shield of Kansas.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

CPT/HCPCS

93797	Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)
93798	Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)
G0422	Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session
G0423	Intensive cardiac rehabilitation; with or without continuous ECG monitoring; without exercise, per session

ICD-10 Diagnoses

I20.8	Other forms of angina pectoris
I20.9	Angina pectoris, unspecified
I21.01	ST elevation (STEMI) myocardial infarction involving left main coronary artery
I21.02	ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery
I21.09	ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall
I21.11	ST elevation (STEMI) myocardial infarction involving right coronary artery
I21.19	ST elevation (STEMI) myocardial infarction involving other coronary artery of inferior wall
I21.21	ST elevation (STEMI) myocardial infarction involving left circumflex coronary artery
I21.29	ST elevation (STEMI) myocardial infarction involving other sites
I21.3	ST elevation (STEMI) myocardial infarction of unspecified site
I21.4	Non-ST elevation (NSTEMI) myocardial infarction
I21.A1	Myocardial infarction type 2
I22.0	Subsequent ST elevation (STEMI) myocardial infarction of anterior wall
I22.1	Subsequent ST elevation (STEMI) myocardial infarction of inferior wall
I22.2	Subsequent non-ST elevation (NSTEMI) myocardial infarction
I22.8	Subsequent ST elevation (STEMI) myocardial infarction of other sites
I22.9	Subsequent ST elevation (STEMI) myocardial infarction of unspecified site
I25.110	Atherosclerotic heart disease of native coronary artery with unstable angina pectoris
I25.111	Atherosclerotic heart disease of native coronary artery with angina pectoris with documented spasm
I25.118	Atherosclerotic heart disease of native coronary artery with other forms of angina pectoris
I25.119	Atherosclerotic heart disease of native coronary artery with unspecified angina pectoris
I25.2	Old myocardial infarction
I25.700	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina pectoris
I25.701	Atherosclerosis of coronary artery bypass graft(s), unspecified, with angina pectoris with documented spasm
I25.708	Atherosclerosis of coronary artery bypass graft(s), unspecified, with other forms of angina pectoris
I25.709	Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris
I25.710	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unstable angina pectoris
I25.711	Atherosclerosis of autologous vein coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.718	Atherosclerosis of autologous vein coronary artery bypass graft(s) with other forms of angina pectoris
I25.719	Atherosclerosis of autologous vein coronary artery bypass graft(s) with unspecified angina pectoris
I25.720	Atherosclerosis of autologous artery coronary artery bypass graft(s) with unstable angina pectoris
I25.721	Atherosclerosis of autologous artery coronary artery bypass graft(s) with angina pectoris with documented spasm

I25.728 Atherosclerosis of autologous artery coronary artery bypass graft(s) with other forms of angina pectoris
I25.729 Atherosclerosis of autologous artery coronary artery bypass graft(s) with unspecified angina pectoris
I25.730 Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unstable angina pectoris
I25.731 Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.738 Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with other forms of angina pectoris
I25.739 Atherosclerosis of nonautologous biological coronary artery bypass graft(s) with unspecified angina pectoris
I25.750 Atherosclerosis of native coronary artery of transplanted heart with unstable angina
I25.751 Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm
I25.758 Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris
I25.759 Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris
I25.760 Atherosclerosis of bypass graft of coronary artery of transplanted heart with unstable angina
I25.761 Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm
I25.768 Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris
I25.769 Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris
I25.790 Atherosclerosis of other coronary artery bypass graft(s) with unstable angina pectoris
I25.791 Atherosclerosis of other coronary artery bypass graft(s) with angina pectoris with documented spasm
I25.798 Atherosclerosis of other coronary artery bypass graft(s) with other forms of angina pectoris
I25.799 Atherosclerosis of other coronary artery bypass graft(s) with unspecified angina pectoris
I50.20 Unspecified systolic (congestive) heart failure
I50.21 Acute systolic (congestive) heart failure
I50.22 Chronic systolic (congestive) heart failure
I50.23 Acute on chronic systolic (congestive) heart failure
I50.30 Unspecified diastolic (congestive) heart failure
I50.31 Acute diastolic (congestive) heart failure
I50.32 Chronic diastolic (congestive) heart failure
I50.33 Acute on chronic diastolic (congestive) heart failure
I50.40 Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.41 Acute combined systolic (congestive) and diastolic (congestive) heart failure
I50.42 Chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.43 Acute on chronic combined systolic (congestive) and diastolic (congestive) heart failure
I50.810 Right heart failure, unspecified

I50.811	Acute right heart failure
I50.812	Chronic right heart failure
I50.813	Acute on chronic right heart failure
I50.814	Right heart failure due to left heart failure
I50.82	Biventricular heart failure
I50.83	High output heart failure
I50.84	End stage heart failure
I50.9	Heart failure, unspecified

REVISIONS

08-17-2010	Policy added to the bcbsks.com web site.
09-24-2012	Description section updated.
	In the Policy section: ▪ In Item E, added "It is preferable that programs start within 90 days of the cardiac event and be completed within 6 months of the cardiac event."
	Rationale section updated.
	Reference section updated.
12-11-2013	Added Medical Policy and Coding Disclaimers.
	Updated Description section.
	In Policy section: ▪ In Item A, added #7, "Compensated heart failure".
	Updated Rationale section.
	In Coding section: ▪ Added ICD-10 Diagnosis codes *(Effective October 1, 2014)*
	Updated Reference section.
07-15-2014	Description section updated
	In Policy section: ▪ Added to A 7 "(Stable congestive heart failure 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)" to define compensated heart failure.
	Revision section updated
	References updated
09-23-2015	Title of policy changed from "Cardiac Rehabilitation Programs"
	Updated Description section.
	In Policy section: ▪ In Item A, removed "items and services" and "who have experienced one or more" and added "outpatient", "programs," "with a history", and "conditions and procedures", to read "Outpatient cardiac rehabilitation programs are considered medically necessary for patients with a history of the following conditions and procedures:" ▪ In Item A 1, added "(MI) (heart attack)", to read "An acute myocardial infarction (MI) (heart attack) within the preceding 12 months; OR" ▪ In Item A 2, added "graft (CABG)", to read "A coronary artery bypass graft (CABG) surgery; OR ▪ In Item A 4, added "surgery" and removed "repair or replacement", to read "Heart valve surgery; OR" ▪ In Item A 6, added "OR", to read "A heart or heart-lung transplant; OR" ▪ In Item A 7, removed "(Stable congestive heart failure 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)"

	▪ In Item B 2, removed ", including education, counseling, and behavioral intervention at least once during the program, tailored to patients' individual needs", to read "Cardiac risk modification" ▪ In Item B 5, removed "for each patient", to read "An individualized treatment plan detailing how components are utilized."
	Updated Rationale section.
	In Coding section: ▪ Removed bullet stating "A single initial visit with the physician for referral to a program may be allowed under CPT code 99215."
	Updated References section.
11-24-2015	In Coding section: ▪ Removed ICD-10 code I20.0.
	Updated References section.
05-11-2016	Updated Description section.
	In Policy section: ▪ Previous Policy Items B, C, D, E, and F were moved to Policy Guidelines section. ▪ In Policy Guidelines, added "each of the above" to Item 1 (previous Policy Item B) to read "An individualized treatment plan detailing how each of the above components are utilized."
	Updated Rationale section.
	Updated References section.
08-18-2017	Updated Description section.
	In Policy section: ▪ Added new Item C, "Intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease or Pritikin Program is considered experimental / investigational." ▪ In Policy Guidelines, removed "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."
	Updated Rationale section.
	In Coding section: ▪ Added HCPCS codes: G0422, G0423.
	Updated References section.
10-01-2017	In Coding section: ▪ Added ICD-10 codes: I21.A1, I50.810, I50.811, I50.812, I50.813, I50.814, I50.82, I50.83, I50.84.
04-11-2018	Updated Description section.
	Updated Rationale section.
	In Coding section: ▪ Removed ICD-9 codes.
	Updated References section.
04-24-2019	Updated Description section.
	Updated Rationale section.
	Updated References section.

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