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Cardiac Rehabilitation (CR)

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None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Outpatient cardiac rehabilitation (CR) programs **may be considered medically necessary** for individuals with a history of one of the following conditions and/or procedures:

- Acute myocardial infarction (MI) (heart attack);
- Coronary artery bypass graft (CABG) surgery;
- Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting;
- Heart valve surgery;
- Heart or heart-lung transplantation;
- Current stable angina pectoris;
- Compensated heart failure; or
- Transmyocardial revascularization.

A cardiac rehabilitation (CR) exercise program **may be considered medically necessary** for three sessions per week up to a 12-week period (36 sessions). Programs are to start within 90 days of the cardiac event and to be completed within six months of the cardiac event.

A comprehensive evaluation **may be considered medically necessary** when performed prior to initiation of CR to evaluate the individual and determine an appropriate exercise program. In addition to a medical examination, an electrocardiogram (ECG) stress test may be performed. An additional stress test may be performed at the completion of the program.

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

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

Intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease, Pritikin Program, or Benson-Henry Institute Program **is considered not medically necessary**.

Virtual cardiac rehabilitation **is considered experimental, investigational and/or unproven.**

Outpatient cardiac **rehabilitation is considered experimental, investigational and/or unproven** for all other indications (e.g., SARS-CoV-2).

Policy Guidelines

None.

Description

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 (CAD) is the most common cause of heart disease. In a 2024 update on heart disease and stroke statistics from the American Heart Association, it was estimated that 720,000 Americans have a new coronary attack (first hospitalized myocardial infarction or coronary heart disease death) and 335,000 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 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

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

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.” The USPHS 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 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 1995 release of the USPHS guidelines, other societies, including in 2005 the American Heart Association (4) and in 2010 the Heart Failure Society of America (5) have developed guidelines on the role of cardiac rehabilitation in patient care.

Rationale

This medical policy was created in August 2003 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through January 23, 2024.

Medical policies 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.

OUTPATIENT CARDIAC REHABILITATION FOR HEART DISEASE

Clinical Context and Therapy Purpose

The purpose of cardiac rehabilitation in individuals who have heart disease is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

Populations

The relevant population of interest is individuals 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.

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.

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.

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. (6) The RCTs included in the meta-analyses enrolled patients with myocardial infarction (MI), coronary heart disease (CHD), angina, percutaneous coronary intervention (PCI), 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 pooled analysis, cardiac rehabilitation was associated with a 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 were Cochrane reviews. One included patients with 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 a comprehensive program). Anderson et al. (2016) updated a 2011 Cochrane review addressing exercise-based cardiac rehabilitation for individuals with CHD. (7, 9) Reviewers included RCTs of exercise-based interventions with at least 6 months of follow-up compared with no-exercise controls in patients with MI, CABG, or PCI, or with angina pectoris or coronary artery disease (CAD). 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 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 PCI 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 (5,783 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 one. Results showed that cardiac rehabilitation had little effect on all-cause mortality over ≤1 year of follow-up (27 trials, 2,596 participants: cardiac rehabilitation 5.1% vs. control 5.8%; low-quality evidence). However, cardiac rehabilitation may make a difference in the long-term (>1 year of follow-up; 6 trials, 2,845 participants: cardiac rehabilitation 17.2% vs. 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% vs. control 23.7%; moderate-quality evidence). Cardiac rehabilitation may also reduce short-term heart failure-related hospital admission (14 trials, 1,114 participants: cardiac rehabilitation 7.1% vs. 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. A 2023 update by Molloy et al. identified 16 new trials. Improvements in all-cause mortality, all-cause hospitalization, and HF-related hospitalization were noted with cardiac rehabilitation in any setting compared with usual care; however, the improvements were only significant for all-cause hospitalization in the short term (RR, 0.69, 95% CI, 0.56-0.86). (11)

Table 1. Systematic Review Characteristics

Study	Dates	Trials	Participants	N. Range	Design
Davies et al. (2010) (8)	1995-2008	29	All adults with chronic systolic HF	3,647 (20 to 2,331)	RCT
Oldridge (2012) (6)	2000-2011	71	Patients with MI, CHD, angina, PCI, and/or CABG	13,824 (6,111 to 10,794)	RCT
Anderson et al. (2016) (7)	1975-2014	63	Patients with MI, angina pectoris, CAD, or who underwent CABG or PCI	14,486 (25 to 3,184)	RCT
Long et al. (2019) (10)	1995-2018	44	Patients with HF	5,783 (19 to 2,331)	RCT
Molloy et al. (2023) (11)	Through December 2021	90	Patients with HF	8728 (NR)	RCT

CABG: coronary artery bypass graft; CAD: coronary artery disease; CHD: coronary heart disease; HF: heart failure; MI: myocardial infarction; N: number; NR: not reported; PCI: percutaneous coronary intervention; RCT: randomized controlled trial.

Table 2. Systematic Review Results

Study	All- Cause Mortality	Cardiovascular Mortality
Davies et al. (2010) (8)	13 studies (≤12 mo)	NR
Difference in pooled mortality, fixed effect RR	1.02	NR
95% CI	0.70 to 1.51	NR
P-value	0.90	NR
Oldridge (2012) (6)	6 studies	6 studies

Reduction, mean %	18.50%	29.4
P-value	<0.05	NR
Range, %	NR	20 to 43
Anderson et al. (2016) (7)	47 studies; N=12,455 participants	27 studies; N=7,469 participants
RR	0.96	0.74
95% CI	0.88-1.04	0.64-0.86
Long et al. (2019) (10)	2,845 participants, 6 studies	(studies did not consistently report deaths due to heart failure)
RR	0.88	NR
95% CI	0.75 to 1.02	NR
Molloy et al. (2023) (11)	3780 participants, 8 studies	NR
RR	0.87 (long-term, > 12 months)	NR
95% CI	0.72 to 1.04	NR

CI: confidence interval; kg: kilogram; ml: milliliter; min: minute; RR: risk ratio; VO^2 Max: maximal oxygen consumption; NR: not reported; mo: months.

Randomized Controlled Trials

Findings of a large, multicenter RCT from the United Kingdom (U.K.) which evaluated the effectiveness of cardiac rehabilitation in a "real-life" setting were published by West et al. (2012). (12) 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 may 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. (13) Finally, these results may in part reflect the degree to which clinically based cardiac rehabilitation programs in the U.K. differ from the treatment protocols used in RCTs that are 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. (14) 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. (15) 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.

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. (16) 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.

Tables 3 and 4 provide a summary of key RCT characteristics and results.

Table 3. Summary of Key RCT Characteristics

Study Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
West et al. (2012); RAMIT (12)	UK	14	1997-2000	Patients diagnosed with acute MI (N=1813)	Cardiac rehabilitation (n=903)	Control (n=910)
Pandey et al. (2017) (14)	US	1	NR	Patients aged ≥ 65 years with HFrEF (n=24) or HFpEF (n=24)	16-week supervised moderate endurance exercise	HRrEF (n=24) vs. HFpEF (n=24)

					training (n=48)	
Opotowsky et al. (2018) (16)	US	1	NR	Patients aged ≥16 years with moderate to severe congenital heart disease (N=28)	12-wk cardiac rehabilitation (n=13)	Standard of care (n=15)

HF: heart failure; HFrEF: HF with reduced ejection fraction; HFpEF: HF with preserved ejection fraction; RCT: randomized controlled trial; MI: myocardial infarction; NR: not reported; UK: United Kingdom; US: United States; RAMIT: Rehabilitation After Myocardial Infarction Trial.

Table 4. Summary of Key RCT Results

Study	**2 Year Mortality**	**Readmissions to Hospital for any Cardiac Condition at 1 Year**	**Training Related Improvement in Vo_2 Peak Change**
West et al. (2012) RAMIT (12)	N=1813 participants	N=1813 participants	NR
CR	82 patients	222 (25%)	NR
Control	84 patients	239 (26%)	NR
RR	0.98	NR	NR
95% CI	0.74-1.30	NR	NR
Pandey et al. (2017) (14)	NR	NR	N=48 participants
HFrEF	NR	NR	18.7+/-17.6
HFpEF	NR	NR	-0.3+/-15.4
P-value	NR	NR	<0.001
Opotowsky et al. (2018) (16)			N=28 participants
CR	NR	NR	+2.2 mL/kg/min (compared to standard of care)
95% CI; p-value	NR	NR	0.7 to 3.7; p=0.002

Cardio: cardiovascular; CR: cardiac rehabilitation; RCT: randomized controlled trial; VO2peak: peak oxygen uptake. CI: confidence interval; HF: heart failure; HFpEF: HF with preserved ejection fraction; HFrEF: HF with reduced ejection fraction; NR: not reported; RR: relative risk; RAMIT: Rehabilitation After Myocardial Infarction Trial.

The purpose of the limitations tables (see 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

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow Up[e]
West et al. (2012); RAMIT (12)					1, 2. Trial was closed prematurely
Pandey et al. (2017) (14)			2. No comparator used		1, 2. Only 16 weeks follow-up
Opotowsky et al. (2018) (16)				1. Key health outcomes such as mortality or readmission not addressed	1, 2. Only 12 weeks follow-up

[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.
RAMIT: Rehabilitation After Myocardial Infarction Trial.

Table 6. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow Up[d]	Power[e]	Statistical[f]
West et al. (2012); RAMIT (12)	3. Allocation concealment unclear	1, 2. Not blinded				
Pandey et al. (2017) (14)	1. Participants not randomly allocated	1, 2. Not blinded				
Opotpwsky et al. (2018) (16)		1, 2. Not blinded			1. Power calculations not reported	

[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.
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 MI. (17) 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 peak oxygen update as a measure of improved exercise capacity. (18) 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 peak oxygen update 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.

Jafri et al. (2021) conducted a retrospective cohort study to evaluate home-based cardiac rehabilitation (HBCR) in patients with established cardiovascular disease. (19) A total of 269

patients at a Veterans Affairs Medical Center were eligible for inclusion (HBCR group, n=157; non-HBCR control group, n=100); 12 patients were excluded due to having outcomes less than 90 days after enrollment (study follow-up period was between 3 to 12 months). A majority of patients (98%) were male, and the mean age was 72 years. The primary outcome was composite all-cause mortality and hospitalizations and secondary outcomes were all-cause hospitalization, all-cause mortality, and cardiovascular hospitalizations. The primary composite outcome occurred in both the HBCR (n=30) and control (n=30) (adjusted hazard ratio [HR], 0.56; 95% CI, 0.33 to 0.95; p=.03). All-cause mortality occurred in 6.4% of HBCR patients versus 13% of the control group (adjusted HR, 0.43; 95% CI, 0.18 to 1.0; p=.05). There was no difference in cardiovascular or all-cause hospitalizations between groups.

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 (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

Clinical Context and Therapy Purpose

The purpose of repeat cardiac rehabilitation in individuals 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 following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals 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.

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.

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 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

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

Section Summary: Repeat Outpatient Cardiac Rehabilitation

For individuals who have been diagnosed with heart disease without a second event who receive repeat outpatient cardiac rehabilitation, the evidence includes no trials.

INTENSIVE CARDIAC REHABILITATION FOR HEART DISEASE

There is no standard definition of an intensive cardiac rehabilitation program and, thus, specific programs are reviewed individually. Three programs have been evaluated by Centers for Medicare & Medicaid Services, and the published evidence supporting these programs is reviewed. 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

Clinical Context and Therapy Purpose

The purpose of the Ornish Program for Reversing Heart Disease in individuals who have diagnosed heart disease is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

Populations

The relevant population of interest is individuals with diagnosed heart disease.

Interventions

The treatment being considered is the Ornish Program for Reversing Heart Disease.

The Ornish Program for Reversing Heart Disease is an intensive cardiac rehabilitation program that focuses on exercise, diet, stress management, and support from others.

The multiple 4-hour sessions are administered by an Ornish-certified physician, cardiac therapist, or other certified health care provider.

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

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 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.

Randomized Controlled Trials
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. (20, 21) Eligibility for the trial included diagnosed coronary artery disease, left ventricular ejection fraction greater than 25%, no MI during the previous 6 weeks, not 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 (i.e., 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

Clinical Context and Therapy Purpose

The purpose of the Pritikin Program in individuals who have diagnosed heart disease is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

Populations

The relevant population of interest is individuals with diagnosed heart disease.

Interventions

The treatment being considered is the Pritikin Program.

The Pritikin Program is an intensive cardiac rehabilitation program based on effective exercise, a healthy diet, and a healthy mindset.

Comparators

The comparator of interest is standard outpatient cardiac rehabilitation. Cardiac rehabilitation includes long-term programs that include medical evaluation, prescribed exercise, modification to reduce cardiac risks, education, and counseling.

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 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.

Nonrandomized Studies

No RCTs evaluating the Pritikin Program were identified. Lakhani et al. (2023) conducted a prospective, nonrandomized study that compared intensive cardiac rehabilitation with the Pritikin Program and traditional outpatient cardiac rehabilitation. (22) The primary outcomes of interest were change in diet quality and quality of life from baseline to visit 24. There was a significant improvement in diet quality but not in quality of life between the Pritikin Program and traditional cardiac rehabilitation groups. Body mass index was also improved in patients who received intensive rehabilitation. Limitations of the study include a short follow-up and lack of data for cardiovascular outcomes.

Racette et al. (2023) published 7-year outcomes from the first institution to implement the Pritiken Program. (23) Retrospective data for 1,507 patients who received the intensive cardiac rehabilitation program and 456 patients who received traditional cardiac rehabilitation were compared. Outcomes of interest (e.g., anthropometric measures, dietary patterns, 6-minute walk distance [6MWD], grip strength, and HRQoL) all improved with the Pritiken Program. Significant benefit of the Pritiken Program compared to traditional cardiac rehabilitation were noted for change in body weight ($p<.0001$), body mass index ($p<.0001$), waist circumference ($p<.0001$), and diet quality as measured by the Rate Your Plate score ($p<.0001$). There was no difference in 6MWD or grip strength between groups. Cardiovascular outcomes, including rehospitalization or mortality, were not assessed.

Table 7. Summary of Ken Nonrandomized Trials

Study	Study Type	Country	Dates	Participants	Intensive cardiac rehabilita-tion	Traditional cardiac rehabilita-tion	Follow-Up
Lakhani et al. (2023) (22)	Cohort	U.S.	2017-2021	Referred by a cardiologist for cardiac rehabilitation	N=230	N=62	24 visits

Racette et al. (2022) (23)	Cohort	U.S.	2013-2019	Enrolled in a cardiac rehabilitation program in the course of usual care	N=1507	N=456	72 sessions over 18 weeks; 7 year follow-up

Table 8. Summary of Key Nonrandomized Trials

Study	Change in diet quality	Change in QOL	Change in body weight (kg)	Change in BMI (kg/m^2)	Change in 6MWD (m)
Lakhani et al. (2023) (22)	N=292	N=292	NR	NR	NR
Intensive cardiac rehabilitation	• 90% improved • 3% no change • 7% worsened	• 80% improved • 7% no change • 13% worsened	NR	NR	NR
Traditional cardiac rehabilitation	• 71% improved • 5% no change • 24% worsened	• 71% IMPROVED • 13% no change • 16% worsened	NR	NR	NR
p-value	.001	NS	NR	NR	NR
Racette et al. (2022) (23)	NR	NR	N=1,963	N=1,963	N=1,963
Intensive cardiac rehabilitation	NR	NR	-1.4±2.8	-0.5±1.0	46.4±57.8
Traditional cardiac rehabilitation	NR	NR	0.1±3.2	0.1±1.1	44.4±58.9
p-value	NR	NR	<.001	<.001	.106

6MWD: 6-minute walk distance; BMI: body mass index; NR: not reported; NS: not significant; QOL: quality of life.

Section Summary: Pritikin Program

No RCTs have evaluated the Pritikin Program; 2 randomized studies in patients with heart disease was identified. Conclusions cannot be drawn from this limited data on the impact on intensive cardiac rehabilitation with the Pritikin Program compared with standard outpatient cardiac rehabilitation.

Benson-Henry Institute Program

Clinical Context and Therapy Purpose

The purpose of the Benson-Henry Institute Program in individuals who have diagnosed heart disease is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

Populations

The relevant population of interest is individuals with diagnosed heart disease.

Interventions

The treatment being considered is the Benson-Henry Institute Program.

The Benson-Henry Institute Program is an intensive cardiac rehabilitation program based on effective exercise, a healthy diet, and a healthy mindset.

Comparators

The comparator of interest is standard outpatient cardiac rehabilitation. Cardiac rehabilitation includes long-term programs that include medical evaluation, prescribed exercise, modification to reduce cardiac risks, education, and counseling.

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 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.

Case-Control Studies

Zeng et al. (2013) reported outcomes of a Medicare-sponsored demonstration of 2 intensive lifestyle modification programs in patients with symptomatic coronary heart disease: the Cardiac Wellness Program of the Benson-Henry Mind Body Institute and the Dr. Dean Ornish Program for Reversing Heart Disease. (24) This analysis included 461 participants and 1795

matched controls using Medicare claims data from 1998 to 2008. Four matched controls were sought for each participant from Medicare claims data, 2 of whom had received traditional cardiac rehabilitation within 12 months following their cardiac events (cardiac rehabilitation controls) and 2 of whom had not (non-cardiac rehabilitation controls). Outcomes included mortality rates during the 3 post-enrollment years, total hospitalizations, hospitalizations with a cardiac-related principal discharge diagnosis, and Medicare-paid costs of care. Of the 324 participants in the Benson-Henry Mind Body Medical Institute program analysis, the authors concluded that during the active intervention and follow-up years, total, cardiac, and non-cardiac hospitalizations were lower in the Benson-Henry program participants than their controls for each comparison ($p<0.001$). The investigators further reported that after year 1, the mortality rate was 1.5% in the Benson-Henry program participants compared with 2.5% and 4.2%, respectively, in cardiac rehabilitation and non-cardiac rehabilitation controls. After year 3, comparable figures were 6.2% in Benson-Henry program participants, 10.5% in cardiac rehabilitation controls, and 11.0% in non-cardiac rehabilitation controls. These mortality differences for the Benson-Henry program participants reached borderline significance ($p=0.08$).

Case Series

Casey et al. (2009) reported the results of a case series that evaluated the effects of an intensive cardiac rehabilitation program, incorporating components of the Benson-Henry Institute Cardiac Wellness Program at a single center. (25) From 1997 to 2005, 637 patients with coronary artery disease were enrolled and completed the program, which consisted of 13 weekly 3 hour sessions with supervised exercise, relaxation techniques, stress management, and behavioral interventions. The mean age of participants was 63 years (range 27 to 92 years); men comprised 72% of the study population. Results revealed significant improvements in clinical (blood pressure, lipids, weight, exercise conditioning, frequency of symptoms of chest pain, and shortness of breath) and psychological outcomes (general severity index, depression, anxiety, and hostility) ($p<0.0001$) with the program.

Section Summary: Benson-Henry Institute Program

No RCTs have evaluated the Benson-Henry Institute Program; a case-control study found the program participants to have lower total, cardiac, and non-cardiac hospitalizations during the active intervention and follow-up years as compared to controls for each comparison. Additionally, program participants had lower mortality rates compared to controls; however, the mortality differences were borderline significant at year 3. A case series also demonstrated that the implementation of components of the Benson-Henry Institute program resulted in an improvement in clinical and psychological outcomes. Conclusions cannot be drawn from these data on the impact of intensive cardiac rehabilitation with the Benson Henry Institute program compared with standard outpatient cardiac rehabilitation.

Post-Acute Cardiac Sequelae of SARS-CoV-2 Infection

Clinical Context and Therapy Purpose

The purpose of outpatient cardiac rehabilitation is to provide a treatment option that is an alternative to or an improvement on standard management without outpatient cardiac rehabilitation.

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

Populations
The relevant population of interest is individuals with post-acute cardiac sequelae of SARS-CoV-2 infection or COVID-19. The Centers for Disease Control and Prevention define the post-acute period as symptoms persisting at 4 or more weeks following infection with SARS-CoV-2. (26) The World Health Organization developed the following consensus case definition of 'post COVID-19 condition': individuals with "a history of probable or confirmed SARS CoV-2 infection, usually 3 months from the onset of COVID-19 with symptoms and that last for at least 2 months and cannot be explained by an alternative diagnosis. Common symptoms include fatigue, shortness of breath, cognitive dysfunction but also others and generally have an impact on everyday functioning. Symptoms may be new onset following initial recovery from an acute COVID-19 episode or persist from the initial illness. Symptoms may also fluctuate or relapse over time." (27)

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.

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.

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 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
Reports of patient rehabilitation after COVID-19 recovery have largely been observational, without clearly identifiable cardiac rehabilitation components within multidisciplinary or cardiorespiratory rehabilitation programs.

No studies specifically assessing the efficacy of cardiac rehabilitation programs for post-acute cardiac sequelae of SARS-CoV-2 infection were identified.

Section Summary: Post-Acute Cardiac Sequelae of SARS-CoV-2 Infection
No direct evidence on the efficacy of cardiac rehabilitation programs in patients with post-acute cardiac sequelae of SARS-CoV-2 infection was identified. Controlled prospective studies in well-defined patient populations with sufficient follow-up duration are necessary to evaluate net health outcomes.

Virtual Cardiac Rehabilitation
Clinical Context and Therapy Purpose
The purpose of virtual cardiac rehabilitation in individuals who have been diagnosed with heart disease is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

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

Interventions
The treatment being considered is virtual cardiac rehabilitation.

Virtual cardiac rehabilitation is HBCR delivered by virtual or remote interactions between patients and providers, including video conferencing, phone, email, text, smartphone applications, or wearable devices.

Comparators
The comparator of interest is standard outpatient cardiac rehabilitation. Cardiac rehabilitation includes longterm programs that include medical evaluation, prescribed exercise, modification to reduce cardiac risks, education, and counseling.

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.

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.

Systematic Reviews

Many meta-analyses/systematic reviews are available for virtual cardiac rehabilitation. (28-33) In general, these reviews have found significant effects on physical activity, cardiovascular risk factors, and quality of life, but evidence for cardiovascular outcomes is limited.

A Cochrane systematic review by McDonagh et al. (2023) compared home-based cardiac rehabilitation (including a variety of virtual methods) with center-based rehabilitation. (34) A total of 24 RCTs were included (N=3046). The meta-analysis did not find a significant difference between home and center-based rehabilitation up to 12 months in the outcomes of: total mortality (risk ratio, 1.19; 95% CI, 0.65 to 2.16) or exercise capacity (standardized mean difference, -0.10; 95% CI, -0.24 to 0.04). The authors concluded that home rehabilitation with or without virtual platforms results in similar clinical outcomes; however, the analysis does not provide adequate information on specific virtual rehabilitation programs.

The analysis by Cruz-Cobo et al. (2022) included 20 randomized studies (N=4,535) of mobile health interventions in patients who had experienced a coronary event. (31) Beneficial effects of mobile health interventions were found for exercise capacity, physical activity, adherence to treatment, and quality of life. All-cause hospital readmission (p=.04) and hospital readmission for cardiovascular causes (p=.05) were statistically lower in the mobile health intervention group compared to the control group, but these may not be clinically relevant differences (point estimates for actual risk differences were -0.03 and -0.04, respectively). There was no difference between groups in mortality. A major limitation of this study is lack of clarity of how many individuals received mobile health interventions for the purpose of cardiac rehabilitation.

Zhou et al. (2023) conducted a systematic review of smartphone-assisted cardiac rehabilitation compared with usual cardiac rehabilitation. (35) A total of 14 RCTs (N=1962) were included and key outcomes included peak oxygen update, 6MWD, compliance, and body mass index (BMI). There were no significant differences in terms of 6MWD (weighted mean difference [WMD], 12.88; 95% CI, -0.82 to 26.57) or BMI (WMD, -0.14; 95% CI, -0.34 to 0.06) between groups; however, peak oxygen update (WMD, 1.32; 95% CI, 0.82 to 1.81) and compliance (WMD, 1.62; 95% CI, 1.21 to 2.17) were improved with smartphone-assisted rehabilitation.

Randomized Controlled Trials

Numerous RCTs with virtual cardiac rehabilitation have been published. (36-46) Of these, only 2 have reported results for cardiovascular outcomes of interest. Indraratna et al. (2022) found

that unplanned hospital readmissions and cardiac readmissions were significantly lower with a smartphone-based intervention to facilitate the transition to outpatient cardiac care (including rehabilitation) compared to usual care among 164 patients being discharged after hospitalization for acute coronary syndrome or heart failure. (39) However, only 100 patients in the study received cardiac rehabilitation after discharge and rehospitalization rates were not provided for this cohort alone. Other limitations of this study include short duration of follow-up (6 months) and that enrollment was terminated in March 2020 so the study may not reflect how usual care is delivered in the post-COVID-19 pandemic era. Piotrowicz et al. (2020) conducted a 9-week RCT of telerehabilitation compared to usual care in 850 patients with heart failure. (41) Both groups had a median follow-up of 793 days. The primary outcome (days alive and out of the hospital through end of follow-up) was similar between groups (median, 775 days [telerehabilitation] vs. 776 days [usual care]). There was also no difference between telerehabilitation and usual care in all-cause hospitalization (HR, 0.913; 95% CI, 0.762 to 1.093), cardiovascular hospitalization (HR, 0.837; 95% CI, 0.667 to 1.050), all-cause mortality (HR, 1.035; 95% CI, 0.706 to 1.517), or cardiovascular mortality (HR, 0.985; 95% CI, 0.619 to 1.569). Since the study only included patients with heart failure, the results may not be applicable to patients with other forms of heart disease. Other limitations include a lack of power for hospitalization and mortality outcomes, and that the cardiac monitoring device used in the study may not reflect the effect of video- or smartphone-based virtual rehabilitation methods used in current practice.

Observational Studies

Nkonde-Price et al. (2022) conducted a retrospective study of virtual cardiac rehabilitation compared to traditional cardiac rehabilitation in a cohort of 2556 patients with cardiovascular disease. (47) Virtual cardiac rehabilitation consisted of home-based cardiac rehabilitation using a mobile phone application linked to a wearable smartwatch, self-directed exercise sessions, weekly nurse phone calls, and health education for 8 weeks. The primary outcome, all-cause hospitalization during 12 months of follow-up, was lower in patients who experienced the virtual cardiac rehabilitation program compared to traditional outpatient cardiac rehabilitation (14.8% vs. 18.1%; OR, 0.79; 95% CI, 0.64 to 0.97; p=.03). There was no difference between groups in 30-day or 90-day all-cause or cardiovascular hospitalization. Mortality was not addressed.

Section Summary: Virtual Cardiac Rehabilitation

Systematic reviews and RCTs suggest that virtual cardiac rehabilitation may have similar effects on cardiovascular outcomes compared to standard outpatient cardiac rehabilitation, but evidence about the effect on hospital readmission is inconsistent. One RCT in patients with heart failure found no difference between virtual cardiac rehabilitation and standard outpatient cardiac rehabilitation on the primary outcome of days alive and out of the hospital. No RCTs have been adequately powered to detect or reported a difference in all-cause mortality or cardiovascular mortality.

Summary of Evidence

For individuals who have diagnosed heart disease who receive outpatient cardiac rehabilitation, the evidence includes multiple randomized controlled trials (RCTs) and systematic reviews of these trials. Relevant outcomes are overall survival (OS), disease-specific survival, symptoms, and morbid events. Meta-analyses of the available trials have found that cardiac rehabilitation improves health outcomes for selected patients, particularly those with coronary heart disease, heart failure, and who have had cardiac surgical interventions. The available evidence has limitations, including lack of blinded outcome assessment, but, for the survival-related outcomes of interest, this limitation is less critical. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have diagnosed heart disease without a second event and receive repeat outpatient cardiac rehabilitation, the evidence includes no trials. Relevant outcomes are OS, 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.

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. Relevant outcomes are OS, 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 that the technology results in an improvement in the net health outcome.

For individuals who have diagnosed heart disease who receive intensive cardiac rehabilitation with the Pritikin Program, the evidence includes 2 nonrandomized studies. Relevant outcomes are OS, 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 that the technology results in an improvement in the net health outcome.

For individuals who have diagnosed heart disease who receive intensive cardiac rehabilitation with the Benson-Henry Institute Program, the evidence includes a case-control study and case series. Relevant outcomes are OS, disease-specific survival, symptoms, and morbid events. Studies are needed that compare the impact of intensive cardiac rehabilitation using the Benson-Henry Institute Program with standard outpatient cardiac rehabilitation programs. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have heart disease due to post-acute sequelae of SARS-CoV-2 infection who receive cardiac rehabilitation in the outpatient setting, no relevant evidence was identified. Relevant outcomes are OS, disease-specific survival, symptoms, and morbid events. Limited reports examining the outcomes of rehabilitation in patients with post-acute COVID-19 have not primarily focused on cardiac rehabilitation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have been diagnosed with heart disease and receive virtual cardiac rehabilitation, the evidence includes systematic reviews/meta-analyses, RCTs, and observational studies. Relevant outcomes are OS, disease-specific survival, symptoms, and morbid events. Meta-analyses have found beneficial effects of virtual cardiac rehabilitation on physical activity and quality of life, but not on cardiovascular hospitalization or mortality. The few available prospective randomized studies have conflicting findings on the effect of virtual cardiac rehabilitation compared to traditional outpatient cardiac rehabilitation for hospital readmission. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American College of Cardiology Foundation/American Heart Association

The 2022 American College of Cardiology (ACC) and the American Heart Association (AHA) heart failure guidelines recommend rehabilitation for Stage C heart failure stating, "In patients with HF, a cardiac rehabilitation program can be useful to improve functional capacity, exercise tolerance, and health-related QOL." (48) In 2023, the ACC/AHA published a statement on supervised exercise training specific to patients with chronic heart failure with preserved ejection fraction (HFpEF) and concluded, "data reviewed herein demonstrate a comparable or larger magnitude of improvement in exercise capacity from supervised exercise training in patients with chronic HFpEF compared with those with heart failure with reduced ejection fraction." (49)

American Heart Association et al.

In 2007, the AHA and the American Association of Cardiovascular and Pulmonary Rehabilitation issued a consensus statement on the core components of cardiac rehabilitation programs. (2) The core components include 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 to be 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. (50) 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 (cardiovascular disease [CVD]) secondary prevention."
- For healthcare organizations, develop and support the following:
  - Maximization of cardiac rehabilitation (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 an evidence-based hybrid approach 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."

The guideline does not use the terminology "virtual" cardiac rehabilitation, but it states that electronic tools such as text messaging, smartphone applications, and wearable sensors may allow patients to follow personalized recommendations for exercise, dietary, and behavioral interventions, and thus expand the number of patients who can participate in cardiac rehabilitation. Other benefits of technology-assisted HBCR include greater patient engagement and patient-provider communication. The panel stated that studies were needed regarding the effect of technology-assisted HBCR on outcomes.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 9.

Table 9. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06077201	Home-Based Cardiac Rehabilitation Using a Novel Mobile Health Exercise Regimen Following Transcatheter Heart Valve Interventions	375	Oct 2026
NCT05933083	MCNAIR Study: coMparative effeCtiveness of iN-person and teleheAlth cardIac Rehabilitation	516	Oct 2027
NCT05972070	Integration of Telemedicine and Home-Based Cardiac Rehabilitation: Feasibility, Efficacy, and Adherence	500	Nov 2024

NCT04245813	Effectiveness of a Cardiac Rehabilitation Program in Patients with Heart Failure	144	May 2023
NCT02984449	Preventive Heart Rehabilitation to Prevent Complications in Patients Undergoing Elective Open Heart Surgery (Heart-ROCQ)	350	Aug 2025
NCT05270993	An Integrative Cardiac Rehabilitation Employing Smartphone Technology (iCREST) for Patients With Post-myocardial Infarction: A Randomized Controlled Trial	124	Dec 2023
NCT05689385	The Effectiveness of eHealth-based Cardiac Rehabilitation in Post-myocardial Infarction Patients ： a Randomized Controlled Trial	150	Dec 2024
NCT05610358	Efficacy of Smartphone Application Based Rehabilitations in Patients With Chronic Respiratory or Cardiovascular Disease	162	Dec 2024
NCT02791685	Smartphone Delivered In-home Cardiopulmonary Rehabilitation	300	Dec 2026

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	93797, 93798
HCPCS Codes	G0422, G0423, S9472

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/15/2024	Document updated with literature review. The following changes were made to Coverage: Added 1) Virtual cardiac rehabilitation is considered experimental, investigational and/or unproven. and 2) Outpatient cardiac rehabilitation is considered experimental, investigational and/or unproven for all other indications (e.g., SARS-CoV-2). References 1, 11, 19 and 26-49 added.

12/15/2023	Document updated with literature review. Coverage unchanged. References 1, 20-21, and 25 added; others removed.
07/01/2022	Reviewed. No changes.
10/01/2021	Document updated with literature review. The following change was made to Coverage: Benson-Henry Institute Program added as not medical necessary. References 1, 5, 10, 15-16, 22-23, and 28 added; others removed.
08/15/2020	Reviewed. No changes.
03/15/2020	Document updated with literature review. The following change was made to Coverage: Intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease or Pritikin Program is now considered not medically necessary instead of experimental, investigational and/or unproven. Added references 20 and 22.
12/01/2018	Document updated with literature review. The following change was made to Coverage: Added an experimental, investigational, and/or unproven statement for intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease or Pritikin Program. Added references 13-19.
07/15/2017	Reviewed. No changes.
09/01/2016	Document updated with literature review. Coverage unchanged.
01/01/2015	Reviewed. No changes.
08/15/2013	Document updated with literature review. The following was added: 1) Coronary stenting and heart-lung transplantation were added to the medically necessary indications and 2) Repeat participation in an outpatient cardiac rehabilitation program in the absence of another qualifying cardiac event was added as experimental, investigational and unproven. CPT/HCPCS code(s) updated
01/01/2010	Codes revised/added/deleted
12/01/2007	Revised updated entire document
08/15/2003	New medical document