Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 9/1/23**
(See policy history boxes for previous effective dates)

Title: Cardiac Rehabilitation, Outpatient

Description/Background

Heart disease is the leading cause of mortality in the United States, accounting for more than half of all deaths. Coronary artery disease is the most common cause of heart disease. In a 2020 update on heart disease and stroke statistics from the American Heart Association, it was estimated that 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 coronary artery disease and various other disorders—structural heart disease and other genetic, metabolic, endocrine, toxic, inflammatory, and infectious causes—can lead to the clinical syndrome of heart failure, of which there are about 650,000 new cases in the United States annually.[2] The SARS2-CoV2 viral infection causes COVID-19 disease. Its effects can result in significant cardiovascular morbidity and mortality with and without prior CVD. A significant proportion of patients may experience long-term complications of SARS2-CoV2 infection (greater than four weeks from the index infection), sometimes called post-acute sequelae COVID-19 syndrome or long hauler's syndrome.[3] Given the burden of heart disease, preventing secondary cardiac events and treating the symptoms of heart disease and heart failure have received much attention from national organizations.

Cardiac Rehabilitation

In 1995, the U.S. Public Health Service defined cardiac rehabilitation services as, in part, "comprehensive, long-term programs involving medical evaluation, prescribed exercise, cardiac risk factor modification, education and counseling. These programs are designed to limit the physiologic and psychological effects of cardiac illness, reduce the risk for sudden death or re-infarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process and enhance the psychosocial and vocational status of selected patients." This U.S. Public Health Service recommended cardiac rehabilitation services for patients with coronary heart disease and 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."[4] Since the release of the U.S. Public Health Service guidelines, other societies, including the American Heart Association (2005)[5] and the Heart Failure Society of America (2010)[6] have developed guidelines about the role of cardiac rehabilitation in patient care.

Cardiac rehabilitation programs are divided into three or more stages or phases:

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

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

Regulatory Status

N/A

Medical Policy Statement

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

Cardiac rehabilitation must be a physician-supervised program that furnishes a prescribed exercise program, cardiac risk factor modification that includes education, counseling, and behavioral intervention as well as psychosocial assessment and outcomes assessment.

Inclusionary and Exclusionary Guidelines

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

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

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

Established codes:

93797 93798

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

S9472

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

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or

worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations."

OUTPATIENT CARDIAC REHABILITATION FOR HEART DISEASE

Clinical Context and Therapy Purpose

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

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

Populations

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

Interventions

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

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.

Review of Evidence

Systematic Reviews
Oldridge (2012) identified 6 independent meta-analyses published since 2000 that reported outcomes from 71 RCTs (N=13824 patients) following cardiac rehabilitation interventions.[7] The RCTs included in the meta-analyses enrolled patients with myocardial infarction, coronary heart disease, angina, percutaneous coronary intervention (PCI), and/or coronary artery bypass graft (CABG). The RCTs compared cardiac rehabilitation programs (exercise only and/or comprehensive rehabilitation) with usual care. Cardiac rehabilitation was associated with a statistically significant ($p<.05$) reduction in all-cause mortality in 4 of the 5 meta-analyses that reported this outcome. In the pooled analysis, cardiac rehabilitation was associated with an 18.5% mean reduction in all-cause mortality. In addition, cardiac rehabilitation was associated with a statistically significant reduction in cardiac mortality in 3 of the 4 meta-analyses that reported disease-specific mortality as an outcome.

Two of the meta-analyses on cardiac rehabilitation were Cochrane reviews. One included patients with coronary heart disease (CHD)[7] and the other focused on patients with systolic heart failure.[9] Both addressed exercise-based cardiac rehabilitation programs (exercise alone or as part of comprehensive program). Anderson et al (2016) updated a 2011 Cochrane review addressing exercise-based cardiac rehabilitation for individuals with CHD.[8,10] Reviewers included RCTs of exercise-based interventions with at least 6 months of follow-up compared with no-exercise controls in patients with myocardial infarction, CABG, or percutaneous coronary intervention, or with angina pectoris or coronary artery disease. The updated review included 63 RCTs (N=14486 individuals), of which 16 trials had been published since the 2011 update. Reviewers reported that the overall risk of bias was unclear, although the quality of reporting improved with more recent trials. Due to the nature of the intervention, patients were not blinded to the treatment group in any of the studies, but 16 (25%) of 62 studies reported details of blinded assessment of study outcomes. In the pooled analysis, cardiac rehabilitation was not significantly associated with overall mortality. However, among 27 studies, cardiac rehabilitation was significantly associated with reduced cardiovascular mortality (292/3850 for cardiac rehabilitation subjects versus 375/3619 for control subjects; relative risk [RR], 0.74;

95% confidence interval [CI], 0.64 to 0.86). Rates of myocardial infarction, CABG, and percutaneous coronary intervention were not significantly associated with receiving cardiac rehabilitation.

Long et al (2019) reported a Cochrane Review of studies assessing cardiac rehabilitation in patients with heart failure. A total of 44 RCTs were evaluated - 11 of which were new trials, for the effects of exercise-based cardiac rehabilitation on adults with heart failure (5783 total participants).[11] A single trial, Exercise Based Cardiac Rehabilitation for Adults With Heart Failure (HF-ACTION), contributed almost half of the patients (with results reported in 18 publications); most other studies were small and single-center. All studies had 6 months or longer follow-up and did not include a formal exercise training intervention as a comparator. The primary outcomes reported were mortality, hospital admission, and health-related quality of life (HRQoL). The overall risk of bias was assessed as being low or unclear, and results were downgraded using the GRADE tool for all outcomes except 1. Results showed that cardiac rehabilitation had little effect on all-cause mortality over ≤1 year of follow-up (27 trials, 2596 participants: cardiac rehabilitation 5.1% versus control 5.8%; low-quality evidence). However, cardiac rehabilitation may make a difference in the long-term (>1 year of follow-up; 6 trials, 2845 participants: cardiac rehabilitation 17.2% versus control 19.6%; high-quality evidence). Mortality related to heart failure was not consistently reported in the studies. Chances of avoiding hospital admission for any cause within 12 months of follow-up were better with cardiac rehabilitation (21 trials, 2182 participants: cardiac rehabilitation 16.5% versus control 23.7%; moderate-quality evidence). Cardiac rehabilitation may also reduce short-term heart failure-related hospital admission (14 trials, 1114 participants: cardiac rehabilitation 7.1% versus control 11.1%; RR 0.59, 95% CI, 0.42 to 0.84; p=.003), 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, participants with heart failure with preserved ejection fraction in recent trials, and more trials of cardiac rehabilitation in a home-based setting, this version may be more valid and applicable.

Table 1. Systematic Review Characteristics

Study	Dates	Trials	Participants	N (Range)	Design
Davies et al (2010)[9]	1995-2008	29	All adults with chronic systolic HF	3,647 (20-2,331)	RCT
Oldridge (2012)[7]	2000-2011	71	Patients with MI, CHD, angina, PCI, and/or CABG	13,824 (6,111-10,794)	RCT
Anderson et al (2016)[8]	1975-2014	63	Patients with MI, angina pectoris, CAD, or who underwent CABG or PCI	14,486 (25-3,184)	RCT
Long et al (2019)[11]	1995-2018	44	Patients with HF	5,783 (19-2,331)	RCT

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

Table 2. Systematic Review Results

Study	All-Cause Mortality	Cardiovascular Mortality
Davies et al (2010)[9]	13 studies (≤12 mo)	NR
Difference in pooled mortality, fixed-effect RR	1.02	NR
95% CI	0.70-1.51	NR
p-value	.90	NR
Oldridge (2012)[7]	6 studies	6 studies
Reduction, mean %	18.50	29.4
p-value	<.05	NR
Range, %	NR	20-43
Anderson et al (2016)[8]	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)[11]	2,845 participants, 6 studies	(studies did not consistently report deaths due to heart failure)
RR	0.88	NR
95 % (CI)	0.75-1.02	NR

CI: confidence interval; NR: not reported; RR: relative risk

Randomized Controlled Trials

Findings of a large, multicenter RCT from the United Kingdom, which evaluated the effectiveness of cardiac rehabilitation in a “real-life” setting were published by West et al (2012).[12] Called the Rehabilitation After Myocardial Infarction Trial (RAMIT), the study included patients from 14 centers with established multifactorial cardiac rehabilitation (including exercise, education, and counseling), involved more than 1 discipline, and provided an intervention lasting a minimum of 10 hours. A total of 1813 patients were randomized:903 to cardiac rehabilitation and 910 to a control condition. Vital status was obtained at 2 years for 99.9% of participants (all but 1 patient) and at 7 to 9 years for 99.4% of patients. By 2 years, 166 patients had died, 82 in the cardiac rehabilitation group and 84 in the control group. The between-group difference in mortality at 2 years (the primary study outcome) was not statistically significant (RR=0.98; 95% CI, 0.74 to 1.30). After 7 to 9 years, 488 patients had died, 245 in the cardiac rehabilitation group and 243 in the control group (RR=0.99; 95% CI, 0.85 to 1.15). In addition, at 1 year, cardiovascular morbidity did not differ significantly between groups. For a combined end point including death, nonfatal myocardial infarction, stroke or revascularization, the RR was 0.96 (95% CI, 0.88 to 1.07). In discussing the study’s negative findings, the trialists noted that medical management of heart disease has improved over time, and patients in the control group might have had better outcomes than in earlier RCTs on this topic. Moreover, an editorial accompanying publication of the trial’s findings emphasized that RAMIT was not an efficacy trial, but rather, a trial evaluating the effectiveness of actual cardiac rehabilitation programs in the United Kingdom.[12] Finally, these results might in part reflect the degree to which clinically-based cardiac rehabilitation programs in the United Kingdom differ from the treatment protocols used in RCTs based in research settings.

A concern raised by the negative findings in the RAMIT trial is that most of the RCTs evaluating cardiac rehabilitation were conducted in an earlier era of heart disease management and may not be relevant to current care. However, RAMIT's results, along with 15 additional RCTs reported since a 2011 Cochrane review, were included in the updated 2016 Cochrane review, which found improvements in cardiovascular mortality associated with exercise-based cardiac rehabilitation.

Pandey et al (2017) evaluated endurance exercise training as part of a cardiac rehabilitation program in a population of heart failure patients stratified by ejection fraction.[14] Participants had heart failure with preserved ejection fraction or reduced ejection fraction, were 65 years of age or older, and had participated in a 16-week exercise program that intensified from 40% to 50% of heart rate reserve in the first 2 weeks to 60% to 70% over the ensuing weeks as part of a previously published RCT.[15] The primary outcome for assessing change in exercise capacity was percentage change in peak oxygen uptake (mL/kg per minute) from baseline to end of exercise training (16-week follow-up). Data on testing from 48 patients (24 reduced ejection fraction, 24 heart failure with preserved ejection fraction) were assessed. Heart failure with preserved ejection fraction patients experienced greater improvement in exercise training patients (18.7%) than reduced ejection faction patients (-0.3%; p<.001) as measured by peak oxygen uptake. There was no information on subsequent hospitalization rates or clinical outcomes such as heart failure progression or mortality. This secondary analysis was used to assert the appropriateness of cardiac rehabilitation in heart failure with preserved ejections fraction patients.

Opotowsky et al (2018) compared cardiac rehabilitation to the standard of care in 28 subjects (mean age: 41.1 years) with moderate to severe congenital heart disease.[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=.16) and a significant improvement in self-assessment of overall health (p<.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 Randomized Controlled Trial Characteristics

Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	***Comparator***
West et al (2012); RAMIT[12]	United Kingdom	14	1997-2000	Patients diagnosed with acute MI (N=1813)	Cardiac rehabilitation (n=903)	Control (n=910)
Pandey et al (2017)[14]	U.S.	1	NR	Patients aged ≥ 65 with HFrEF (n=24) or HFpEF (n=24)	16-wk supervised moderate endurance exercise training (n=48)	HRrEF (n=24) vs. HFpEF (n=24)

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

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

Table 4. Summary of Key Randomized Controlled Trial Results

Study	2-yr Mortality	Readmission to Hospital for Any Cardiac Condition at 1 y	Training-Related Improvement in Vo2 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	<.001
Opotowsky et al (2018)[16]			
CR	NR	NT	+2.2 mL/kg/min (compared to standard of care)
95% CI; p value	NR	NR	0.7 to 3.7; p=.002

CI: confidence interval; CR: cardiac rehabilitation; HF: heart failure; HFpEF: HF with preserved ejection fraction; HFrEF: HF with reduced ejection fraction; NR: not reported; RCT: randomized controlled trial; RR: relative risk; Vo_2peak: peak ox; RAMIT: Rehabilitation After Myocardial Infarction Trial.

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

Table 5. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
West et al (2012); RAMIT[12]	4,5. Descriptions of diversity in study populations were not reported				1,2. Trial was closed prematurely
Pandey et al (2017)[14]	4. Enrolled populations do not reflect relevant diversity; 81% of participants were White		2. No comparator used		1,2. Only 16 wks follow-up
Opotowsky et al (2018)[16]	4,5. Descriptions of diversity in study populations were not reported			1. Key health outcomes such as mortality or readmission not addressed	1,2. Only 12 wks follow-up

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

a Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest; 5. Other.
c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
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; 7. Other.
e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.
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				
Opotowsky et al (2018)[16]		1,2. Not blinded			1. Power calculations Not reported	

The study limitations 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
e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Com RAMIT: Rehabilitation After Myocardial Infarction Trial.

Observational Studies

Sumner et al (2017) published a systematic review of controlled observational studies evaluating cardiac rehabilitation in patients diagnosed with acute myocardial infarction.[17] Cardiac rehabilitation interventions consisted of structured multicomponent programs that included exercise and at least 1 of the following: education, information, health behavior change, and psychological or social support. Usual care interventions, generally supervised medical interventions, were the control conditions. Ten studies met reviewers' eligibility criteria. In a meta-analysis of 5 studies reporting all-cause mortality (an unadjusted outcome), there was a significantly lower risk of death in the group that received cardiac rehabilitation (odds ratio [OR], 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 (OR, 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 (OR, 0.21; 95% CI, 0.12 to 0.37). Only 1 study reported an adjusted analysis of cardiac-related mortality, so data could not be pooled.

Nilsson et al (2018) investigated the effect of a 12-week cardiac rehabilitation program with a high-intensity interval exercise component using participant peak oxygen uptake as a measure

of improved exercise capacity.[18] Increased exercise capacity has been shown to improve survival among persons with coronary heart disease. The objective of the study was to assess whether this addition to a cardiac rehabilitation program yielded improved long-term results. One hundred thirty-three coronary patients participated in this prospective cohort study and were evaluated at baseline, at the end of the 12-week program, and again at a 15-month follow-up. Additional test measurements included a cardiopulmonary exercise test, body mass index, blood pressure tests, and quality of life questionnaire. Of the 133 patients, 86 patients had complete information for the 15-month follow-up. Mean peak oxygen uptake improved from a baseline of 31.9 mL/kg/min to 35.9 mL/kg/min (p<.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. 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 reduction in all-cause mortality and/or cardiac mortality. The available evidence has limitations, including lack of blinded outcome assessment, but, for the survival-related outcomes of interest, this limitation is less critical.

REPEAT OUTPATIENT CARDIAC REHABILITATION

Clinical Context and Therapy Purpose

The purpose of repeat cardiac rehabilitation in patients who have heart disease without a second event is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

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

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

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 principles described in the first indication.

REVIEW OF EVIDENCE

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

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.

Virtual Cardiac Rehabilitation

Clinical Context and Therapy Purpose

The purpose of virtual cardiac rehabilitation in patients 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 review.

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 (home based cardiac rehabilitation) 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 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.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

Review of Evidence

Systematic Reviews

The analysis by Cruz-Cobo et al (2022) included 20 randomized studies (N=4535) of mobile health interventions in patients who had experienced a coronary event.[28.] 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.

These innovative virtual home-based CR programs are multiplying with remote monitoring trackers that can help cardiac patients to manage their heart disease and medication

(therapeutic education) and promote healthy diet and increased physical activity. The use of trackers to quantify physical activity may lead patients to adopt an active lifestyle while ensuring safety. Moreover, patients should be able to contact the health care team at any time. The interface should be able to record and send variables (energy expenditure, body mass, glycemia, blood pressure, heart rate, electrocardiogram [ECG], etc) measured via sensors to a web platform accessible to the physician, cardiologist, exercise specialists, and nurses. Virtual home-based CR trials have been done in a number of countries. Some experiences have shown convincing data both in terms of feasibility, safety, and improvement of cardiovascular risk factors. However, some challenges remain, such as the issues of privacy data and the ability to engage older patients. Real-time monitoring, such as ECG and blood pressure bandwidth measurement during exercise is also an issue.

(Choxi 2021)[29] Available evidence suggests that Home Based Cardiac Rehabilitation (HBCR) may provide an alternative option for CR services for stable low- to moderate-risk patients with CVD who lack available CBCR services. Shorter-term improvements in functional capacity, HRQOL, and CVD risk factor control are similar in HBCR and CBCR, and longer-term studies on the impact of HBCR on clinical events are still lacking. Further study is recommended to assess the impact of HBCR services in more diverse and higher-risk groups of patients and to assess the impact of hybrid models of CR, including components from both. Also, safety data is needed for HBCR, particularly in higher-risk groups.

The overall effectiveness of HBCR compared with CBCR is generally difficult to attribute to a single particular component, particularly in those studies that included bundled interventions comprising exercise training, dietary counseling, weight management, psychological support, and blood pressure and lipid management. Which components were most influential or how particular program or setting characteristics influenced patients and health outcomes is difficult to ascertain because of the diversity of patient characteristics, the length and intensity of programs, and the mechanisms of delivery. It has been reported that lifestyle changes that occur during CBCR can deteriorate when CBCR interventions are withdrawn.[60] It is possible that the higher degree of self-monitoring/management and un-supervised exercise inherent in HBCR programs compared with CBCR may make the transition from active intervention to lifelong disease self-management more seamless, but this needs further investigation. In addition, the generalizability of findings from these studies is very limited for nonwhite ethnic minorities, individuals in lower socioeconomic groups, individuals who are uninsured or underinsured, older adults, and women because these groups were significantly underrepresented in the studies reviewed.

(Randal et al. 2019)[30] Summarized new delivery strategies are needed to improve participation. One potential strategy is home-based CR (HBCR). Compared to standard facility-based CR services, which are provided in a medically supervised facility, HBCR relies on remote coaching with indirect exercise supervision and is provided mostly or entirely outside of the traditional center-based setting. One potential approach is alternative site or home-based CR (HBCR) which can be carried out in a variety of settings, including the home or other nonclinical settings such as community centers, health clubs and parks. In concept, home based cardiac rehab (HBCR) could help overcome some of the barriers that community based cardiac rehab programs face, including geographic, logistical, and other access-related

barriers. Although home-based exercise training is commonly recommended by CBCR staff for their patients on days when they are not physically present in the CBCR center, “stand alone” HBCR programs are still in their infancy. However, the European guidelines on CVD prevention state that “home-based rehabilitation with and without telemonitoring holds promise for increasing participation and supporting behavioral change”. In addition, Cochrane collaborative reviews of CR have combined randomized studies of CBCR and HBCR trials, and a recent comparison of CBCR and HBCR has concluded that there is low to moderate strength evidence that HBCR and CBCR have similar effects on quality of life and cost among patients with recent MI or coronary revascularization. Several meta-analyses/systematic reviews are available for virtual cardiac rehabilitation.[25,26,27,28,29,30,] 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. There was no reduction in all-cause mortality.

Randomized Controlled Trials

Numerous RCTs with virtual cardiac rehabilitation have been published.[31,32,33,34,35,36,37,38,39,40,41,42,43] 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.[35] 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 included short duration of follow-up (6 months) and that enrollment was terminated in March 2020. 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.[37] 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.

Retrospective Studies

Nkonde-Price et al (2022)[44] conducted a retrospective study of virtual cardiac rehabilitation compared to traditional cardiac rehabilitation in a cohort of 2556 patients with cardiovascular disease.[42,] 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 been diagnosed with heart disease and receive outpatient cardiac rehabilitation, the evidence includes multiple randomized controlled trials (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 been diagnosed with heart disease without a second event and receive repeat outpatient cardiac rehabilitation, the evidence includes no trials. Relevant outcomes are overall survival, disease-specific survival, symptoms, and morbid events. No studies were identified evaluating the effectiveness of repeat participation in a cardiac rehabilitation program. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have been diagnosed with heart disease and receive virtual cardiac rehabilitation, the evidence includes systematic reviews/meta-analyses, RCTs, and retrospective 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.

SUPPLEMENTAL INFORMATION

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

PRACTICE GUIDELINES AND POSITION STATEMENTS

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Physicians

In 2012, the American College of Physicians and 6 other cardiology associations published joint guidelines on the management of stable ischemic heart disease.[20] The guidelines included the following statement on cardiac rehabilitation: "Medically supervised exercise programs, (cardiac rehabilitation) and physician-directed, home-based programs are recommended for at-risk patients at first diagnosis." The 2014 update to the guideline did not include additional information on cardiac rehabilitation.[21]

American College of Cardiology Foundation

In 2013, the American College of Cardiology Foundation and the American Heart Association updated their joint guidelines on the management of heart failure.[22] These guidelines included the following Class IIA recommendation on cardiac rehabilitation (level of evidence: B): "Cardiac rehabilitation can be useful in clinically stable patients with heart failure to improve functional capacity, exercise duration, health-related quality of life, and mortality." The 2022 guideline did not include additional information on cardiac rehabilitation.[23]

American Heart Association

In 2007, the American Heart Association and the American Association of Cardiovascular and Pulmonary Rehabilitation issued an updated consensus statement on the core components of cardiac rehabilitation programs.[2] The core components included patient assessment before beginning the program, nutritional counseling, weight management, blood pressure management, lipid management, diabetes management, tobacco cessation, psychosocial management, physical activity counseling, and exercise training. Programs that only offered supervised exercise training were not considered cardiac rehabilitation. The guidelines specified the assessment, interventions, and expected outcomes for each of the core components. For example, symptom-limited exercise testing before exercise training was strongly recommended. The guidelines did not specify the optimal overall length of programs or the 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.(HBCR)[24] They make the following suggestions for healthcare providers:

- Recommend center-based cardiac rehabilitation (CBCR) to all eligible patients.
- As an alternative, recommend (HBCR) to clinically stable low- and moderate-risk patients who cannot attend CBCR.
- Design and test HBCR "using effective processes of care for CVD [cardiovascular disease] 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 evidence-based hybrid approached to CR" that are optimized for each patient and that "promote long-term adherence and favorable behavior change."
- For CR professionals, "work with other healthcare professionals and policymakers to implement additional research and...expand the evidence base for HBCR."

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.

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

Medicare National Coverage

Cardiac Rehabilitation

Since 1989, Medicare has had a national coverage determination for cardiac rehabilitation. In 2010, there was a change in Medicare coverage for cardiac rehabilitation.[50] Indications for coverage remained the same; namely, patients who have experienced at least 1 of the following:

- Acute myocardial infarction within the preceding 12 months
- Coronary artery bypass surgery
- Current stable angina pectoris
- Heart valve repair or replacement
- Percutaneous transluminal coronary angioplasty or coronary stenting
- Heart or heart-lung transplant

As of February 2014, patient eligibility criteria were expanded for cardiac rehabilitation to include patients with the following: "Stable, chronic heart failure, defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks. Stable

patients are defined as patients who have not had recent (≤6 weeks) or planned (≤6 months) major cardiovascular hospitalizations or procedures." [51]
The 2010 criteria specify the required components of cardiac rehabilitation programs. Programs must include all of the following[50]:

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

In January 2010, the criteria on the frequency and duration of cardiac rehabilitation services were updated[50]
"Cardiac rehabilitation items and services must be furnished in a physician's office or a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all time items and services are being furnished under the program….
…[C]ardiac rehabilitation program sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over/up to 36 weeks, with the option of an additional 36 sessions over an extended period of time if approved by the Medicare contractor."
In October 2020, virtual cardiac rehabilitation and intensive cardiac rehabilitation were added to the list of telehealth services that Medicare would cover during the COVID-19 public health emergency.[52] Virtual cardiac rehabilitation will continue to be covered through the end of 2023.[53,54]

Ongoing and Unpublished Clinical Trials

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

Table 7. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04245813	Effectiveness of a Cardiac Rehabilitation Program in Patients With Heart Failure	144	May 2023
NCT02984449	Preventive Heart Rehabilitation in Patients Undergoing Elective Open Heart Surgery to Prevent Complications and to Improve Quality of Life (Heart-ROCQ) - A Prospective Randomized Open Controlled Trial, Blinded End-point (PROBE)	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
Unpublished			
NCT03218891	Cardiac Rehabilitation in Patients With Refractory Angina	72	Feb 2022
NCT05489913	The Effect ofWeb Based Cardiac Rehabilitation Support on the Healthy Lifestyle Behaviors, Medication Adherence and Quality of Life in Coronary Artery Patients	70	Jun 2021

NCT: national clinical trial.

Government Regulations

National:

Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, Section 232 Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished on or after January 1, 2010
(Rev. 11426; Issued: 05-20-22; Effective: 01-01-22; Implementation: 07-05-22)

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

Covered Conditions:

As specified in 42 CFR 410.49, Medicare Part B covers CR and ICR for beneficiaries who have experienced one or more of the following

• An acute myocardial infarction within the preceding 12 months;
• A coronary artery bypass surgery;
• Current stable angina pectoris;
• Heart valve repair or replacement;
• Percutaneous transluminal coronary angioplasty or coronary stenting;
• A heart or heart-lung transplant.
• Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal medical therapy for at least 6 weeks, on or after February 18, 2014 for CR and on or after February 9, 2018 for ICR; or

• Other cardiac conditions as specified through a national coverage determination (NCD). The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

CR and ICR programs must include all of the following:

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

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

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

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

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

As specified at 42 CFR 410.49(f)(1), CR program sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare Administrative Contractor (MAC).

As specified at 42 CFR 410.49(f)(1), the number of CR sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare Administrative Contractor (MAC). As specified at 42 CFR 410.49(f)(2), ICR sessions are limited to 72 1-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks.

CR and ICR Settings:

Medicare Part B pays for CR and ICR in a physician's office or a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision for physician office services as specified at 42 CFR 410.26, and for hospital outpatient services as specified at 42 CFR 410.27.

Medicare Claims Processing Manual, Chapter 32, Section 140.2 Cardiac Rehabilitation Program Services Furnished On or After January 1, 2010
(Rev. 11426; Issued: 05-20-22; Effective: 01-01-22; Implementation: 07-05-22

As specified at 42 CFR 410.49, Medicare covers cardiac rehabilitation program services for beneficiaries who have experienced one or more of the following:

- An acute myocardial infarction within the preceding 12 months; or
- A coronary artery bypass surgery; or
- Current stable angina pectoris; or
- Heart valve repair or replacement; or
- Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; or
- A heart or heart-lung transplant.
- Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks, on or after February 18, 2014; or
- Other cardiac conditions as specified through a national coverage determination (NCD).

Cardiac rehabilitation programs must include all of the following components:

- Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished;
- Cardiac risk factor modification, including education, counseling, and behavioral intervention at least once during the program, tailored to patients' individual needs;
- Psychosocial assessment;
- Outcomes assessment; and
- An individualized treatment plan detailing how components are utilized for each patient. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

Cardiac rehabilitation items and services must be furnished in a physician's office or a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all time items and services are being furnished under the program. This provision is satisfied if the physician meets the requirements for the direct supervision for physician office services as specified at 42 CFR 410.26 and for hospital outpatient therapeutic services as specified at 42 CFR 410.27.

As specified at 42 CFR 410.49(f)(1), cardiac rehabilitation program sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks, with the option for an additional 36 sessions over an extended period of time if approved by the Medicare contractor.

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

A. General
As per sections 1861(s)(2)(CC) and 1861(eee)(1) of the Social Security Act, items and services furnished under a Cardiac Rehabilitation (CR) program may be covered under Medicare Part B. Among other things, Medicare regulations at 42CFR410.49 define key terms, address the components of a CR program, establish the standards for physician supervision, and limit the maximum number of program sessions that may be furnished. The regulations also describe the cardiac conditions that would enable a beneficiary to obtain CR services. Effective for dates of service on and after January 1, 2010, coverage is permitted for beneficiaries who have experienced one or more of the following:

- Acute myocardial infarction within the preceding 12 months
- Coronary artery bypasses surgery
- Current stable angina pectoris
- Heart valve repair or replacement
- Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting
- A heart or heart-lung transplant
  The Centers for Medicare & Medicaid Services (CMS) may add "other cardiac conditions as specified through a national coverage determination" (See 42 CFR §410.49(b)(1)(vii).

Indications and Limitations of Coverage
B. Nationally Covered Indications
Effective for dates of service on and after February 18, 2014, CMS has determined that the evidence is sufficient to expand coverage for cardiac rehabilitation services under 42 CFR §410.49(b)(1)(vii) to beneficiaries with stable, chronic heart failure, defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least six weeks. Stable patients are defined as patients who have not had recent ($\leq$ 6 weeks) or planned ($\leq$ 6 months) major cardiovascular hospitalizations or procedures. (See section A above for other indications covered under 42 CFR §410.49(b)(1)(vii).

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

Local:
There is no local coverage determination on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Intensive Cardiac Rehabilitation
Pulmonary Rehabilitation

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/9/23, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
6/25/02	6/25/02	6/25/02	Joint policy established
9/27/03	9/27/03	10/14/03	Routine maintenance
4/11/05	4/11/05	4/19/05	Routine maintenance
1/1/08	10/16/07	11/15/07	Routine maintenance
3/1/09	12/9/08	12/21/08	Routine maintenance
3/1/10	12/8/09	12/8/09	Routine maintenance
3/1/11	1/4/11	1/4/11	Routine maintenance
1/1/13	10/16/12	10/16/12	Routine maintenance; updated information under the Government Regulations section.
1/1/14	10/15/13	10/25/13	Routine maintenance
1/1/15	10/21/14	11/3/14	Routine maintenance, updated information under the Government Regulations section.
3/1/16	12/10/15	12/10/15	Routine maintenance
3/1/17	12/13/16	12/13/16	Routine maintenance
11/1/17	9/15/17	9/27/17	Routine maintenance Removed phase I from exclusions Added “documented within the last 12 months” to indications listed under inclusions
9/1/18	6/19/18	6/18/19	Routine maintenance
9/1/19	6/18/19		Routine maintenance
9/1/20	6/16/20		Routine maintenance
9/1/21	6/15/21		Routine maintenance. Added ref 1,15, 16
9/1/22	6/21/22		Routine maintenance Ref 19 added
11/1/22	8/16/22		Routine maintenance Ref 3 added (ls)
9/1/23	6/26/23		Routine maintenance (jf)

			Vendor Managed: NA Added new ref: 25-44 The association removed reference 17 and replaced it with an updated reference 36. Removed from description: Approximately 10-20% of hospitalized patients can have evidence of myocardial injury in the setting of acute COVID-19. Added to exclusion: Virtual cardiac rehabilitation is considered investigational

Next Review Date: 2nd Qtr, 2024

BLUE CARE NETWORK BENEFIT COVERAGE POLICY: CARDIAC REHABILITATION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; policy criteria apply
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

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

- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.