Medical Coverage Policy

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Cardiac Rehabilitation (Phase II Outpatient)

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Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers

must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses cardiac rehabilitation (Phase II) services that are provided on an outpatient basis post facility discharge.

Coverage Policy

Coverage for cardiac rehabilitation (CR) varies across plans. Refer to the customer's benefit plan document for coverage details.

If benefit coverage is available for cardiac rehabilitation, then the following conditions apply.

A medically supervised outpatient Phase II Cardiac Rehabilitation program (CPT®* code 93797, 93798) is considered medically necessary within six months of ANY of the following events:

- acute myocardial infarction (MI)
- coronary artery bypass grafting (CABG)
- percutaneous coronary vessel remodeling
- valve replacement or repair
- coronary artery disease (CAD) associated with chronic stable angina that has failed to respond adequately to pharmacotherapy and is interfering with the ability to perform age-related activities of daily living and/or impairing functional abilities
- heart failure that has failed to respond adequately to pharmacotherapy and is interfering with the ability to perform age-related activities of daily living and/or impairing functional abilities
- following surgical septal myectomy via thoracotomy
- heart transplantation or heart-lung transplantation
- major pulmonary surgery, great vessel surgery, or MAZE arrhythmia surgery
- placement of a ventricular assist device
- sustained ventricular tachycardia or fibrillation
- survivors of sudden cardiac arrest

When medical necessity for outpatient Phase II Cardiac Rehabilitation has been established, the program must meet ALL of the following requirements:

- direct supervision by a physician or nurse practitioner/physician assistant
- physician prescribed exercise each session
- cardiac risk factor modification
- psychosocial assessment
- individualized treatment plan
- outcome assessment

- provides a maximum of two one-hour sessions per day for up to thirty six sessions (most commonly two to three sessions per week for twelve to eighteen weeks)

Additional cardiac rehabilitation services are considered medically necessary, based on the above listed criteria, when the individual has ANY of the following conditions:

- another documented myocardial infarction or extension of initial infarction
- another cardiovascular surgery or angioplasty
- new evidence of ischemia on an exercise test, including thallium scan
- new, clinically significant coronary lesions documented by cardiac catheterization

EACH of the following is considered educational and/or training in nature and not medically necessary:

- phase III or IV cardiac rehabilitation programs
- intensive cardiac rehabilitation programs (HCPCS code G0422, G0423) (e.g. Pritikin Program, Ornish Program for Reversing Heart Disease, Benson-Henry Institute Cardiac Wellness Program)

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Socioeconomic status as measured by several individual (e.g., income, education attainment, occupation, medical assistance such as Medicaid) and environmental indicators (e.g., area deprivation index or median income based on zip code data) has been shown to have a significant impact on cardiovascular disease (CVD) development and outcomes. Individuals with low socioeconomic status (SES) and CVD face a disproportionately higher risk of recurrent events and mortality compared to those with high SES.

In spite of the known benefits, cardiac rehabilitation (CR) programs are consistently underutilized. It is estimated that less than 40% of eligible patients enroll in CR after a qualifying event. A major factor is the under-referral of patients to CR, especially women, older adults, and under-represented racial and ethnic groups. According to an analysis by Oehler et al. (2023), those living in a rural setting are also more likely to underutilize cardiac rehabilitation services. Referral rates for women are approximately 10% lower than for men, even after adjusting for age and comorbid conditions. Lack of transportation, lack of enjoyment, and home responsibilities are cited more frequently by women as reasons for nonparticipation.

Black patients are referred 20% less frequently than are non-Hispanic white patients. Enrollment is also low, as Black patients participate in CR half as often as white patients (17.3% vs. 30%). These findings are particularly concerning, as women and non-whites are significantly more likely to die within five years after a first myocardial infarction, compared with white male patients. One

proposed solution is for hospitals to implement an automated referral process, to prevent referral bias (Mathews and Brewer, 2021; Balady, et al., 2011).

Rural patients face enrollment challenges because of limited access. An American Heart Association (AHA) presidential advisory named poor rural access to phase II CR as a contributing factor to poor cardiovascular outcomes. Those living more than 15 miles from a CR center are 71% less likely to be enrolled than are those who live less than 1.5 miles away. Additionally, virtual models might be problematic in rural areas because of limited broadband internet access (24% of households do not have broadband internet in urban settings vs. 32% of households in rural settings).

Finally, there is a gradual drop in participation in CR as patients age, dropping to one-third of baseline values in those over 85 years old. Older age and functional and sensory impairments common in aging may lead to lower rates of participation. Virtual, home-based interventions suggest benefit.

General Background

Center-Based Cardiac Rehabilitation

The 2005 American Heart Association/American Association of Cardiovascular and Pulmonary Rehabilitation (AHA/AACVPR) scientific statement defines cardiac rehabilitation (CR) as coordinated, multifaceted interventions designed to optimize a cardiac patient's physical, psychological, and social functioning, in addition to stabilizing, slowing, or even reversing the progression of the underlying atherosclerotic processes, thereby reducing morbidity and mortality (Leon, et al., 2005). CR typically incorporates exercise training, patient education, and health behavior modification to improve outcomes in individuals with cardiovascular disease.

The candidates for CR/secondary prevention programs are patients who recently have had a myocardial infarction (MI); have undergone coronary artery bypass graft surgery (CABG) or percutaneous coronary interventions; heart transplant candidates or recipients; or patients with stable chronic heart failure, peripheral arterial disease with claudication, or other forms of cardiovascular disease or cardiac surgical procedures (Leon, et al., 2005).

CR/secondary prevention programs currently include baseline patient assessments, nutritional counseling, aggressive risk-factor management (i.e., lipids, hypertension, weight, diabetes, and smoking), psychosocial and vocational counseling, and physical activity counseling and exercise training. Additionally, CR programs include the appropriate use of cardioprotective drugs that have evidence-based efficacy for secondary prevention (Leon, et al., 2005).

The early CR programs initiated mobilization after a myocardial infarction and were referred to as Phase I or inpatient CR. The goal was to condition the patient to safely carry out activities of daily living following discharge. Such programs entailed prescribing activity in rigid steps with successively higher metabolic equivalents (METs). Comprehensive CR programs eventually grew to include three to four phases.

- **Phase I (Inpatient):** Inpatient rehabilitation, usually lasting for the duration of hospitalization for an acute coronary event or surgery. It emphasizes a gradual, progressive approach to exercise and an education program that helps the patient understand the disease process, the rehabilitation process, and initial preventive efforts to slow the progression of disease. Submaximal exercise testing before hospital discharge is

done to provide important prognostic information and help restore patient confidence. These programs are uncommon due to the brevity of most hospital stays.

- **Phase II (Outpatient Medically Supervised):** Multifaceted, physician-directed outpatient rehabilitation, lasting from hospital discharge to 2–12 weeks later. Phase II CR emphasizes safe physical activity to improve conditioning with continued behavior modification aimed at smoking cessation, weight loss, healthy eating, and other factors to reduce disease risk.

- **Phase III (Supervised, Transitional):** Supervised rehabilitation, often in a group setting, lasting 6–12 months. Establishes a prescription for safe exercise that can be performed at home or in a community service facility, such as a senior center, and continues to emphasize risk-factor reduction while transitioning to independence.

- **Phase IV (Maintenance/Follow-Up):** This is usually an indefinite program, and some programs may combine Phases III and IV. The goal is to encourage lifelong adherence to the healthy habits established during Phase II. Follow-up visits can occur at 6–12 month intervals. Blood pressure and pulse measurement, serum lipid levels, and even repeat maximal exercise tolerance tests can provide useful feedback to the patient and indicate areas that may require lifestyle changes to minimize coronary events.

Phase II (Outpatient) Cardiac Rehabilitation (CR)
Phase II CR is described by the U.S. Public Health Service as consisting of "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 of sudden death or reinfarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the psychosocial and vocational status of selected patients." CR programs aim to reduce subsequent cardiovascular related morbidity and mortality. Phase II CR specifically refers to outpatient, medically supervised programs that provide both electrocardiogram (ECG) monitored and non-electrocardiogram (ECG) monitored sessions. The programs are typically initiated within one to three weeks after hospital discharge and generally administered within the six months following discharge from the hospital (Bartels, et al., 2024).

It is recommended that patients referred to CR undergo a symptom-limited exercise tolerance/stress test before entering the CR program. The exercise test is to exclude important symptoms, ischemia, or arrhythmias that might require other interventions before exercise training. The exercise test also serves to establish baseline exercise capacity and to determine maximum heart rate for use in preparing an exercise prescription. These tests are generally done with the patient on their usual medications to mimic the heart rate response likely to occur during exercise training. Exercise intensity is regulated by monitoring peak heart rate. The exercise training modalities used during Phase II, as in Phase I, usually consist of walking and stationary bicycling, and the patient and family are educated about coronary risk and self-monitoring.

Most Phase II exercise programs consist of three sessions per week for 12 weeks, however the frequency and duration may be impacted by the level of cardiac risk stratification. The CR program is individualized by assessing the patient's history and current need for cardiac risk factor modification. Risk stratification is used to identify patients at risk for death or reinfarction, and to provide guidelines for the rehabilitative process.

Each cardiac rehabilitation session is individualized to meet the patient's needs. Exercise training is the principal component of the program, as it results in increased peak exercise capacity, usually expressed in METs. The MET is the total oxygen requirement of the body, with one MET

equal to 3.5 milliliters of oxygen consumed per kilogram of body weight per minute. Exercise training is aimed to improve MET capacity, resulting in improved oxygen delivery and extraction, by exercising skeletal muscles, decreasing the cardiovascular requirements of exercise and increasing the amount of work that can be done before ischemia (i.e., blood deficiency) occurs.

Contraindications to the exercise program component of CR include the following (Davis, 2019):

- unstable angina
- resting systolic blood pressure >200 mm Hg or diastolic BP >100 mm Hg
- orthostatic blood pressure drop or drop during exercise training of >20 mm Hg
- third-degree heart block
- resting ST displacement (> 3 mm)
- uncontrolled diabetes
- acute systemic illness or fever
- recent embolism
- active pericarditis or myocarditis
- moderate to severe aortic stenosis
- thrombophlebitis
- uncontrolled arrhythmias
- uncontrolled congestive heart failure (CHF)
- orthopedic problems that prohibit exercise

Centers for Medicare and Medicaid Services (CMS)
CMS currently covers CR for the following indications (CMS, 2024):

- a documented acute myocardial infarction (AMI) within the preceding 12 months
- CABG surgery
- stable angina pectoris
- heart valve replacement/repair
- percutaneous transluminal coronary angioplasty (PTCA) or coronary artery stenting
- heart or heart/lung transplant
- 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)
- other cardiac conditions as specified through a national coverage determination (NCD)

CMS lists the following cardiac rehabilitation program requirements:

- 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 individual needs.
- Psychosocial assessment; outcomes assessment; and an individualized treatment plan detailing how components are utilized for each individual.
- Outcomes assessment.
- An individualized treatment plan detailing how components are utilized for each patient, established, reviewed, and signed by a physician every 30 days.

In 2010, CMS updated criteria on the frequency and duration of cardiac rehabilitation services stating that cardiac rehabilitation items and services must be furnished in a physician’s office or a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times items and services are being furnished under the program. Cardiac rehabilitation program sessions are limited to a maximum of

two 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.

Literature Review
Several Cochrane systematic reviews and meta-analyses of randomized controlled trials have evaluated the effectiveness of center-based cardiac rehabilitation (CR) for numerous indications, including heart failure, post-heart transplantation, post-myocardial infarction, and after percutaneous coronary intervention (PCI). Overall, the evidentiary analyses have concluded that CR, particularly exercise-based CR, confers clinically important improvements in exercise capacity and quality of life, and lowers the risk of rehospitalization and death (Molloy, et al., 2024; Gore, et al., 2023; Abraham, et al., 2021; Dibben, et al., 2021; Nielsen, et al., 2019; Long, et al., 2018; Anderson, et al., 2017a; Risom, et al., 2017; Anderson and Taylor, 2014).

Clark et al. (2005), from the University of Alberta Evidence-based Practice Center for the AHRQ Technology Assessment Program, conducted a meta-analysis of coronary heart disease management programs. The purpose of the study was to determine the effectiveness of secondary cardiac prevention programs with and without exercise components. The interventions tested in the trials, and frequency and duration of the interventions, varied substantially among the studies. The studies enrolled highly selected patient populations. After reviewing 63 randomized controlled trials of 21,295 patients with coronary disease, the authors concluded that secondary prevention programs for patients already diagnosed with cardiac disease improved processes of care, enhanced quality of life/function status, reduced recurrent myocardial infarctions, reduced hospitalizations, and reduced long-term mortality in patients with established CAD.

Professional Societies/Organizations
Evidence-based professional society guidelines consistently and strongly recommend comprehensive center-based cardiac rehabilitation (CR) in the management and prevention of cardiovascular disease.

In developing the guidelines below, the American College of Cardiology (ACC)/American Heart Association (AHA) guideline task force used evidence-based methodologies to assign each recommendation a Class of Recommendation and a Level of Evidence.

The Class of Recommendation indicates the degree of benefit versus risk and corresponds to the strength of the recommendation. The Level of Evidence indicates the certainty of the evidence supporting the recommendation; based on the type, size, quality, and consistency of the evidence reviewed. The class and evidence levels were updated in 2015 and 2019 to further refine the definitions and better reflect the evidence upon which the recommendation is based (Lawton, et al., 2022; Halperin, et al., 2016; O'Gara, et al., 2013).

Class (Strength) of Recommendation	
Guidelines published prior to August 2015	Guidelines published after August 2015
Class I • Benefit >>> Risk • Procedure/Treatment should be performed/administered.	Class 1 (Strong) • Benefit >>> Risk • Intervention is recommended; is indicated/useful/effective/beneficial

Class IIa • Benefit >> Risk • Additional studies with focused objectives needed • It is reasonable to perform procedure/ administer treatment	Class 2a (Moderate) • Benefit >> Risk • Intervention is reasonable; can be useful/effective/beneficial
Class IIb • Benefit ≥ Risk • Additional studies with broad objectives needed; additional registry data would be helpful • Procedure/treatment may be considered	Class 2b (Weak) • Benefit ≥ Risk • Intervention may be reasonable; may be considered; its usefulness/ effectiveness is unknown/unclear/ uncertain or not well-established
Class III • Risk ≥ Benefit • Procedure/treatment should not be performed/administered, since it is not helpful and may be harmful	Class 3: No Benefit (Moderate) • Benefit = Risk • Intervention is not recommended/ indicated/useful/effective/beneficial; it should not be performed/ administered
	Class 3: Harm (Strong) • Risk > Benefit • Intervention is potentially harmful; causes harm; is associated with excess morbidity/mortality; should not be performed/administered

Level of Evidence (LOE)	
Guidelines published prior to August 2015	Guidelines published after August 2015
Level A • Multiple populations evaluated • Data derived from multiple randomized clinical trials (RCTs) or meta-analyses	Level A • High-quality evidence from more than 1 RCT • Meta-analyses of high-quality RCTs • One or more RCTs corroborated by high-quality registry studies
Level B • Limited populations evaluated • Data derived from a single randomized trial or nonrandomized studies	Level B-R (Randomized) • Moderate-quality evidence from 1 or more RCTs • Meta-analyses of moderate-quality RCTs

<table>
<tr><th colspan="2">Level of Evidence (LOE)</th></tr>
<tr><td>Guidelines published prior to August 2015</td><td>Guidelines published after August 2015</td></tr>
<tr><td></td><td>Level B-NR (Nonrandomized)
Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
Meta-analyses of such studies</td></tr>
<tr><td rowspan="2">Level C
Very limited populations evaluated
Only consensus opinion of experts, case studies, or standard of care</td><td>Level C-LD (Limited Data)
Randomized or nonrandomized observational or registry studies with design or execution limitations
Meta-analyses of such studies
Physiological or mechanistic studies in human subjects</td></tr>
<tr><td>Level C-EO (Expert Opinion)
Consensus of expert opinion based on clinical experience</td></tr>
</table>

The 2022 AHA/ACC/Heart Failure Society of America (HFSA) guideline for the management of heart failure recommends exercise training (or regular physical activity) for patients with heart failure who are able to participate, to improve functional status, exercise performance, and quality of life (Class 1; Level of Evidence: A). Further, in patients with heart failure, a cardiac rehabilitation program can be useful to improve functional capacity, exercise tolerance, and health-related quality of life (Class 2a; Level of Evidence: B-NR) (Heidenreich, et al., 2022).

The 2021 ACC/AHA/Society for Cardiovascular Angiography and Interventions (SCAI) guideline for coronary artery revascularization recommends that patients who have undergone revascularization should be prescribed a comprehensive cardiac rehabilitation program prior to hospital discharge or at the first outpatient visit, to reduce deaths and hospital readmissions and improve quality of life (Class: 1; Level of Evidence: A). Further, the guideline recommends that these patients should be educated about cardiovascular disease risk factors and how to modify them to reduce cardiovascular events (Class: 1; Level of Evidence: C-LD) (Lawton, et al., 2022).

The ACC/AHA clinical performance and quality measures for CR were updated most recently in 2018. The 2018 document retires the original "Set B" measures while publishing six new performance measures and three quality measures. These measures focus on the opportunities to improve referrals to outpatient CR from both inpatient and outpatient presentations. The updated performance measures state all patients hospitalized and evaluated in outpatient setting with a primary diagnosis of an acute myocardial infarction (MI) or chronic stable angina (CSA), or who during hospitalization have undergone coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation are to be referred to an early outpatient cardiac rehabilitation/secondary prevention (CR) program. Furthermore, the performance measures state all patients evaluated in the inpatient and outpatient setting who within the past 12 months have a primary diagnosis of heart failure with reduced ejection fraction be referred to outpatient exercise training, typically delivered in an outpatient CR program. The remaining performance measures and quality measures focus on enrollment, adherence and clinical outcomes of the CR program. The authors noted that improved

clinical outcomes are realized with a "full dose" of 36 prescribed sessions. CR communication to healthcare providers is important and care coordination is considered standard of care. The patients who are appropriate for entry into a CR program include persons 18 years of age or older who, during the previous year, have had one or more of the qualifying diagnoses previously noted. (Thomas, et al., 2007, 2010, 2018).

The 2014 focused update to the 2007 American College of Cardiology Foundation (ACCF)/AHA guideline for the management of patients with non-ST-elevation MI/acute coronary syndrome recommends referral to a comprehensive cardiac rehabilitation program either before hospital discharge or during the first outpatient visit. (Class I; Level of Evidence: B) (Amsterdam, et al., 2014).

The 2013 update of the 2004 ACCF/AHA practice guideline for the management of patients with ST-elevation myocardial infarction (STEMI) states, under posthospitalization plan of care, that exercise-based cardiac rehabilitation/secondary prevention programs are recommended for patients with STEMI (Class I; Level of Evidence: B) (O'Gara, et al., 2013). There has been no update to this guideline since 2013.

The 2012 ACCF/AHA/SCAI/American College of Physicians (ACP)/American Association for Thoracic Surgery (AATS)/Preventive Cardiovascular Nurses Association (PCNA)/Society of Thoracic Surgeons (STS) guideline for the diagnosis and management of patients with stable ischemic heart disease stated that medically supervised cardiac rehabilitation programs and physician-directed, home-based programs are recommended for at-risk patients at first diagnosis. (Class I; Level of Evidence: A) (Fihn, et al., 2012). The 2014 focused update of this guideline did not address cardiac rehabilitation.

The updated 2011 AHA/ACCF secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular disease guideline recommendations for cardiac rehabilitation states:

- All eligible patients with acute coronary syndrome (ACS) or whose status is immediately post coronary artery bypass surgery or post-PCI should be referred to a comprehensive outpatient cardiovascular rehabilitation program either prior to hospital discharge or during the first follow-up office visit (Class I; Level of Evidence: A).
- All eligible outpatients with the diagnosis of ACS, coronary artery bypass surgery or PCI (Class I; Level of Evidence: A), chronic angina (Class I; Level of Evidence: B), and/or peripheral artery disease (Class I; Level of Evidence: A) within the past year should be referred to a comprehensive outpatient cardiovascular rehabilitation program.
- A home-based cardiac rehabilitation program can be substituted for a supervised, center-based program for low-risk patients (Class I; Level of Evidence: A).
- A comprehensive exercise-based outpatient cardiac rehabilitation program can be safe and beneficial for clinically stable outpatients with a history of heart failure (Class IIa; Level of Evidence: B) (Smith, et al., 2011).

The 2011 AHA guidelines for the prevention of cardiovascular disease (CVD) in women indicated that a comprehensive CVD risk-reduction program (e.g., cardiovascular or stroke rehabilitation; physician-guided home- or community-based exercise training program) should be recommended to women with a recent acute coronary syndrome or coronary revascularization, new-onset or chronic angina, recent cerebrovascular event, peripheral arterial disease (Class I; Level of Evidence: A) or current/prior symptoms of heart failure and an LVEF ≤ 35% (Class I; Level of Evidence B) (Mosca, et al., 2011).

In 2007, the AHA and the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) updated their 2000 scientific statement addressing the core components of CR/secondary prevention programs. The update presents the current information on the evaluation, interventions, and expected outcomes in each of the core components of CR/secondary prevention programs, including baseline patient assessment, nutritional counseling, risk factor management (lipids, blood pressure, weight, diabetes mellitus, and smoking), psychosocial interventions, and physical activity counseling and exercise training. Symptom-limited exercise testing is strongly recommended prior to participation in an exercise-based CR program. The evaluation may be repeated as changes in clinical condition warrant. Test parameters should include assessment of heart rate and rhythm, signs, symptoms, ST-segment changes, hemodynamics, perceived exertion, and exercise capacity. On the basis of patient assessment and the exercise test if performed, it is recommended to risk stratify the patient to determine the level of supervision and monitoring required during exercise training (Balady, et al., 2007).

Virtual/Remote, Home-Based and/or Hybrid Cardiac Rehabilitation

In recent years, an increasing number of alternative strategy programs have emerged to combat the low utilization of center-based CR, including home- or community-based ("remote"), virtual, and hybrid programs. These alternative programs vary in structure, length, and implementation, but generally rely on remote coaching with indirect exercise supervision that occurs outside of the traditional outpatient center or office setting. Technologies range from virtual, app-based programs that allow for real-time, two-way audiovisual communication between the individual and rehabilitation staff, to more remote programs which utilize only intermittent interaction via phone, email, and/or mail.

The proposed advantages of such programs include convenience and flexibility, which purportedly increase enrollment and adherence, especially among individuals who otherwise would be unable or unwilling to attend a center-based program. Barriers to implementing such programs include health data and privacy concerns; inequitable access to the required technology and/or broadband service; variable technology literacy; depersonalization of the patient-provider relationship; reliance on self-reported outcomes; and unknown accuracy and reliability of digital technologies (e.g., wearable biosensors). Nonetheless, published evidence generally supports the safety and efficacy of virtual, home-based and hybrid CR programs. Further, several professional societies support the use of these alternate CR modalities, particularly by those individuals who are unable or unwilling to attend a center-based CR program (Maddox, et al., 2024; Golbus, et al., 2023; Ghisi, et al., 2022; Thomas, et al., 2019).

Literature Review
Evidence in the peer-reviewed published scientific literature comparing home-based CR to no formal CR (i.e., medical management only), and/or to traditional, center-based CR programs consists of randomized controlled trials, prospective noncomparative trials, retrospective reviews, and meta-analyses. Most trials involve short-term follow-up (i.e., ≤ 12 months), and vary widely in terms of CR program elements, program length, control groups, inclusion/exclusion criteria, outcome measures, and data reporting. Generally, studies have found that, compared to individuals who did not participate in a formal CR program, individuals in home-based CR programs saw significant improvements in exercise capacity and health-related quality of life scores, and reduced risk of hospitalization and death. Further, many studies have found no significant differences in outcomes between individuals who took part in center-based CR and those who participated in virtual/home-based CR (Molloy, et al., 2024; Krishnamurthi, et al., 2023; Tegegne, et al., 2022; Cavalheiro, et al., 2021; Jin, et al., 2019; Hwang, et al., 2017; Smolis-Bąk, et al., 2015; Lear, et al., 2014).

In the Hybrid Comprehensive Telerehabilitation in Heart Failure Patients (TELEREH-HF) randomized clinical trial, Piotrowicz et al. (2020) evaluated the effects of a hybrid rehab program on clinical outcomes in patients with heart failure (HF), compared to usual care. The primary study hypothesis was that HCTR benefits would be maintained on follow up, with an increased probability of a longer percentage of days alive and out of the hospital. The study was conducted across five centers in Poland, and included 850 participants. The intervention consisted of a nine-week hybrid comprehensive telerehabilitation (HCTR) program, wherein the initial (one week) stage was conducted in a hospital setting, follow by eight weeks of home-based HCTR performed five times weekly. Telerehabilitation was facilitated by a clinical team and monitoring center which received and stored data from a remote tele-ECG device, transmitted via mobile phone. The tele-ECG device included preprogrammed training sessions with defined parameters. The patients in the usual care (UC) group underwent baseline clinical testing during a three-day hospitalization, remained under observation until the end of the ninth week, and received usual care as appropriate. Some UC patients participated in rehabilitation, and some of them had remote monitoring of their existing implanted cardiovascular electronic devices (CIEDs). Inclusion criteria for the study were: diagnosis of left ventricular (LV) systolic HF; LV ejection fraction ≤ 40%; New York Heart Association (NYHA) Class I-III; hospitalization within six months prior to study; and clinically stable. There were many exclusion criteria, including: NYHA Class IV; history of heart transplant; active malignancy with prognosis <2-5 years; left ventricular assist device or biventricular assist device; or recent percutaneous angioplasty, coronary artery bypass graft, pacemaker placement, or cardiac resynchronization therapy device implantation. The primary outcomes measured were mortality and hospitalizations. Other outcomes assessed included change in cardiopulmonary exercise test duration; peak VO_2; percentage of anticipated peak VO_2; change in 6-minute walk test distance; quality-of-life; and change in NYHA class. Follow ups were completed at 14 months and 26 months. Thirty-two (3.8%) of subjects were lost to follow up. The study did not meet its primary outcome of extending the percentage of days alive and out of the hospital during the 14-26 months of follow up. The probability that HCTR extends the percentage of days alive and out of the hospital versus UC was 0.49 (95% CI, 0.46-0.53; p=0.74). Mortality rates at 24 months were 12.5% in the HCTR group and 12.4% in the UC group (hazard ratio [HR], 1.03 [95% CI, 0.70-1.51]). At nine weeks, the HCTR group improved significantly more than the UC group in key measures: the change in 6-minute walk test distance was 30.0 meters versus 20.7 meters, respectively (p=0.01); the change in peak VO_2 was 0.95 mL/kg/min versus 0.00 mL/kg/min, respectively (p<0.001); the change in quality of life was 1.6 points versus 0.00 points, respectively (p=0.008); and improvement in NYHA class was greater in the HCTR group than in the UC group (p<0.001). No deaths or serious adverse events occurred during or immediately after telemonitored exercise. During the nine-week intervention period, there were two deaths in each group (HCTR and UC). Limitations of the study included a mixed comparator (12% of patients in the UC group participated in a CR program); possible heterogeneity of treatment effect according to treatment site; lack of functional status and quality of life data beyond the intervention period; and women accounted for only 11.5% of the patient population.

Song et al. (2020) conducted a prospective randomized controlled trial (n=106) to evaluate the effect of smartphone-based telemonitored cardiac rehabilitation (CR) among recently discharged coronary heart disease patients. Subjects were randomized into two groups, instructed in an individualized exercise program, and underwent cardiopulmonary exercise testing. The monitored group received smartphone-based telemonitored CR which measured exercise frequency, blood pressure and heart rate before and after exercise, and self-reported post-exercise fatigue. The control group received an exercise regimen upon hospital discharge, then routine follow up only. Subjects were included who were age ≤ 75 years with stable coronary heart disease, and ability to correctly use the software. Exclusion criteria were: congestive heart failure class III–IV under the New York Heart Association (NYHA) classification, severe disease (cancer, HIV, kidney/liver disease), or being unable or unwilling to exercise. The study measured exercise tolerance by VO_2 peak, changes in exercise habits, biochemical blood test and echocardiography parameters,

control rate of blood lipids and glucose, and adverse events. Follow up was at six months (single follow up; 10 subjects overall [9.4%] were lost to follow up). Outcomes for the monitored group showed significant improvement in exercise tolerance, as represented by VO_2 peak of 22.29 ± 4.79 (mL/kg/min) versus 19.07 ± 5.33 (mL/kg/min) for the control group (p=0.003); significantly higher exercise compliance (93.8% versus 77.1% in the control group) (p=0.020); and no significant differences in echocardiography or biochemical blood test parameters, blood lipid or blood glucose control rates. There were no adverse events. Author-noted limitations included variations in smartphone use, communication methods, and researcher feedback, and no long-term follow up. Further noted limitations were the small patient population; comparator that was routine follow up (without CR) rather than traditional center-based CR; underrepresentation of women; relatively young mean age; and low-risk patients.

In a prospective randomized controlled trial (n=179), Snoek et al. (2020) aimed to evaluate the effectiveness of home-based, mobile guided cardiac rehabilitation (CR) as an alternative for elderly patients who declined participation in a center-based CR program. The intervention group received six months of home-based CR with telemonitoring and coaching. Participants were given a smartphone and heart rate belt, and instructed to exercise at moderate intensity for at least 30 minutes per day, five days per week. Data was collected via the smartphone app, and reviewed by the program staff who then provided motivational interviewing via weekly telephone contacts in the first month, bimonthly in the second month, and monthly thereafter up to six months. In the subsequent six months, patients received no further coaching or feedback. Patients in the control group did not receive any form of CR throughout the study period, but rather received locally-defined standard of care. Inclusion criteria were: age 65 years or older; recent diagnosis of acute coronary syndrome (ACS), coronary revascularization, surgical or percutaneous treatment for valvular disease, and coronary artery disease (CAD); and having declined participation in center-based CR. Exclusion criteria were: contraindication to CR, mental impairment leading to inability to cooperate, severely impaired ability to exercise, signs of severe cardiac ischemia, insufficient knowledge of the native language, or an implanted cardiac device. Outcome measures included peak oxygen uptake (VO_2 peak), blood lipids, HbA1c, blood pressure (BP), quality of life, anxiety, and depression. Follow up was completed at six months and 12 months; 28 (15.6%) were lost to follow up. At six months, the intervention group had significantly increased VO_2 peak ($p<0.001$) and peak workload (p=0.001), whereas the control group showed no significant change in these parameters. HDL had significantly increased in both groups after six months (intervention: $p<0.001$, control: p=0.002), and the control group had a significant decrease in diastolic BP (p=0.03) whereas the intervention group had no significant change. At 12 months, the intervention group VO_2 peak, peak workload, and HDL remained significantly improved (p=0.001, $p<0.001$, and p=0.002, respectively), and diastolic BP had decreased significantly from baseline (p=0.01). The control group also showed significant improvement in peak workload, diastolic BP, HDL, and HbA1c (p=0.02, p=0.05, p=0.001, and p=0.004, respectively) as compared to baseline. There were no significant changes or variances in the remaining outcomes. Adverse events included one cardiovascular (CV)-related death and 11 CV-related hospitalizations among participants in the intervention group, while the control group reported no deaths and 10 CV-related hospitalizations. There was no statistically significant difference between the groups in terms of adverse events (p=0.66). The study was limited by the comparator being medical standard of care (without CR), an exercise-only approach (rather than comprehensive CR), and six-month duration (compared to the United States standard of 12-18 weeks). Additionally, there was an underrepresentation of women and non-Caucasians, and considerable loss to follow up (15%). The study demonstrated that there may be a benefit of enrollment in a home-based CR program for those patients who would otherwise refuse CR altogether, however future studies are warranted to evaluate the long-term clinical benefits and safety of such a program.

Dorje et al. (2019) conducted a randomized controlled trial (n=312) which assessed the effectiveness of a smartphone-based cardiac rehabilitation (CR) program delivered via the social

media platform WeChat (SMART-CR/SP program), as compared to usual care (without structured CR). The program consisted of a two-month intensive course followed by a four-month step-down phase. SMART-CR/SP integrated WeChat with peripheral devices to measure and report blood pressure (BP), heart rate (HR), and subjective symptoms. Education was delivered via cartoon-format modules. Feedback on progress was provided by a rehab coach via WeChat. Study participants had undergone percutaneous coronary intervention related to coronary heart disease. Patients with contraindications to exercise rehabilitation, an inability to operate a smartphone, no internet access, or a pre-existing comorbid condition with limited life expectancy were excluded from the study. The control group received standard care, which involved health education prior to inpatient hospital discharge, and as needed follow up visits with a cardiologist. Outcome measures included change in functional capacity (measured by six-minute walk distance), adverse events, disease process awareness, resting HR, systolic BP, medication adherence, blood chemical profile, health-related habits, and varied psychosocial measures. Follow ups occurred at two, six, and 12 months (only partial data was gathered at endpoint). Up to 15% were lost to follow up. The improvement in six-minute walk distance at two and six months was significantly greater in the intervention group as compared to the control group ($p=0.034$; $p=0.027$, respectively). The intervention group also showed significantly higher coronary heart disease knowledge scores and CR/secondary prevention needs assessment scores at two and six months ($p<0.0001$). At the six-month follow-up, systolic BP and HR were significantly lower in the intervention group than in the control group ($p=0.029$; $p=0.039$, respectively). At 12 months, total and LDL cholesterol were significantly lower in the intervention group than in the control group ($p=0.018$; $p=0.016$, respectively). Intervention group participants showed greater adherence to measured core cardioprotective medications at two months ($p=0.0048$), six months ($p=0.019$), and 12 months ($p=0.011$). The remaining outcomes and points of follow up showed no significant differences. Adverse-event analysis was defined as the percentage of participants who discontinued the study owing to adverse events; none were reported. Author-noted limitations included: single-hospital study, potential selection bias, young and stable cohort, and inability to complete a cost-effectiveness analysis. Additional limitations include the number of patients lost to follow up, potential underreporting of adverse events, and use of a unique social media platform (WeChat) which can’t be generalized to other programs.

A Cochrane systematic review and meta-analysis of 23 randomized controlled trials (n=2,890 participants) by Anderson et al. (2017b) compared the impact of home-based and center-based cardiac rehabilitation (CR) on mortality and morbidity, exercise capacity, and other outcomes in patients with heart disease. The home-based CR programs included in the review were structured, included exercise training, had clear objectives, and included monitoring, follow up visits, letters or telephone calls from staff, or at least self-monitoring diaries. The length, intensity, and specific nature of the exercise programs and monitoring varied among the programs. The control groups were center-based CR in a variety of settings (e.g. hospital physiotherapy department, university gymnasium, community sports center). Some programs (both home and control) were exercise-only, while others were comprehensive in nature. Patient inclusion criteria were age over 18 years, and one of the following: post myocardial infarction (MI), prior revascularization, and diagnosis of angina or heart failure (HF). Exclusion criteria were: patients who had undergone heart transplants, had implantable cardioverter defibrillators (ICDs) or cardiac resynchronization therapy, or who had previously undergone CR. Outcome measures varied, and included total mortality, cardiac events, exercise capacity assessed by validated outcome measure (e.g. VO_2 peak, 6 minute walk test), validated measures of health-related quality of life, adherence, modifiable coronary risk factors, and costs and health service use. Follow ups typically ranged from 2-12 months, with three studies reporting data beyond 12 months. Loss to follow-up varied considerably among studies and was asymmetric across home- and center-based CR groups. Only a few trials examined the impact of losses to follow-up. Nine studies reported less than 20% attrition, four studies reported greater than 20% attrition, seven studies provided incomplete

data, and three studies provided no data on attrition. Between-group outcomes up to 12 months included the following:

- Total mortality: No significant difference (based on data from 11 studies)
- Cardiac events: Not poolable, small number of studies reported data
- Exercise capacity: No significant difference
- Health-related Quality of life: Not poolable, wide variation
- Withdrawal: No significant difference (inconsistent reporting)
- Modifiable coronary risk factors: No significant difference
- Adherence: Not poolable, wide variation
- Cost and health service use: Not poolable; (home-based CR was less expensive in four studies, more expensive in one study)

Author-noted limitations included: inconsistent reporting of outcomes, considerable statistical heterogeneity across a number of outcomes among trials, short duration of most studies, and often poorly reported details of interventions making it difficult to assess whether the CR programs used would meet current standards of good practice. Additionally, there was significant heterogeneity of home CR programs as they varied in design, duration, frequency, and technological involvement (if any). Most studies included only lower-risk individuals. There was consistent underrepresentation of women. Finally, studies older than 10 years were included in the analysis.

An update to the above Cochrane systematic review and meta-analysis by Anderson et al. was published in 2023. McDonagh et al. included three new trials; a total of 24 trials (n=3046 participants) were included in the analysis. The updated review continued to find no significant differences between home- and center-based CR in the primary outcomes up to 12 months of follow-up: total mortality (risk ratio [RR] = 1.19, 95% confidence interval [CI] 0.65 to 2.16; low-certainty evidence); and exercise capacity (standardized mean difference (SMD) = -0.10, 95% CI -0.24 to 0.04; low-certainty evidence). Most studies showed no significant difference between home- and center-based CR in health-related quality of life up to 24 months follow-up. The authors concluded that both home and center-based CR, when formally supported by healthcare staff, were similarly effective in improving clinical and health-related quality of life outcomes in individuals post-myocardial infarction, post-revascularization, or with heart failure. Additional research is needed to whether the positive short-term effects of home CR programs can be confirmed in the long term (McDonagh, et al., 2023).

Reid et al. (2012) conducted a randomized controlled trial (n=223) to determine whether patients who used the CardioFit internet-based physical activity program were more physically active following hospitalization for coronary heart disease (CHD) than patients who received usual care only. The trial included patients age 20-80 years old, admitted for acute coronary syndrome who underwent successful percutaneous coronary revascularization, and who did not intend to enroll in traditional cardiac rehabilitation. During their hospitalization, participants in the intervention group received an individually-tailored physical activity plan generated by the CardioFit program, which was reviewed with them by an exercise specialist. After discharge, participants logged their daily activity on the CardioFit website and completed a series of online tutorials over a six-month period. Following each tutorial, a new physical activity plan was developed. Participants also received emails from the exercise specialist providing motivational feedback on progress. The usual care group received physical activity guidance from their attending cardiologist and an educational booklet. Excluded from the trial were patients who underwent coronary artery bypass graft (CABG) surgery, had an implantable cardioverter-defibrillator, or had NYHA Class III or IV heart failure. The outcomes measured were physical activity level (average number of steps per day over seven days, as measured by pedometer and self-reported), self-reported leisure-time physical activity, and heart disease health-related quality of life. Follow ups were completed at six and 12 months. Seventy participants (31.4%) were lost to follow up. Overall, the intervention group had a significantly higher average step count compared to the usual care group (average of

764 more steps more per day; p=0.023). The intervention group also had significantly higher self-reported physical activity (p=0.047), and higher heart disease health-related quality of life scores in emotional (p=0.038) and physical (p=0.031) dimensions, as compared to the control group. There were no other significant differences in outcomes. Adverse events included: deaths (n=2, control), CABG (n=1, control), and rehospitalization for chest pain (n=6 control; n=4 intervention). Limitations of the study include: significant (>30%) loss to follow up, exercise regimen generated by a proprietary program without physician oversight, and potential incorrect or incomplete data due to self-reporting of pedometer readings and activity. Although not statistically significant, the control group had a greater number of: smokers, subjects with higher body mass index, diabetics, subjects with prior MI and prior PCI; and lower mean pre-hospitalization physical activity.

Professional Societies/Organizations
In 2019, the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), American Heart Association (AHA), and American College of Cardiology (ACC) issued a scientific statement on home-based cardiac rehabilitation focusing on the problem of underutilization of CR programs, despite its well-established benefits. The statement suggests one potential approach to resolving this issue is the expansion of home- or community-based CR programs, to help overcome geographic, logistical, and other access-related barriers facing traditional center-based CR programs. In particular, the suggestion is that home-based CR is a suitable and safe alternative option for CR services for stable, low- to moderate-risk patients with cardiovascular disease who lack available center-based services. Longer-term studies on the impact of home-based CR programs, as well as safety data (particularly for high-risk groups), remain lacking. Therefore thorough clinical evaluation with risk stratification is critical to ensure appropriate referral to home-based CR (Thomas, et al., 2019).

The 2024 ACC Expert Consensus Decision Pathway for the treatment of heart failure with reduced ejection fraction (HFrEF) supported the feasibility of remote telerehabilitation for patients with HFrEF who lack access to outpatient cardiac rehabilitation, citing studies that reported high adherence rates with such programs (Maddox, et al., 2024).

Outpatient Intensive Cardiac Rehabilitation Programs

Several outpatient intensive cardiac rehabilitation (ICR) programs have been developed including, but not limited to, the Pritikin Program, the Ornish Program for Reversing Heart Disease, and the Benson-Henry Institute Cardiac Wellness Program (Hayes, 2018, Updated 2020; CMS, 2010; 2014). ICR are comprehensive, long-term programs involving medical evaluation, exercise, cardiac risk factor modification, education, and counseling for patients with chronic or post-acute cardiovascular disease. The Pritikin, Ornish, and Benson-Henry Institute programs are commercial, licensed products with varying program design. Common features include specific diet prescription, group support meetings, and a focus on lifestyle modification. Ongoing wellness education classes, self-guided practice, and group sessions can continue for a year or more. ICR programs include phase III and IV elements which are considered educational and training in nature. There is a lack of large randomized prospective comparative studies in the peer-reviewed published literature that outpatient intensive cardiac rehabilitation programs improve health outcomes compared to a program of traditional outpatient cardiac rehabilitation.

A 2018 Hayes Comparative Effectiveness Review (updated 2020) evaluated the comparative effectiveness and safety of intensive cardiac rehabilitation (ICR) programs relative to usual care (UC) and conventional cardiac rehabilitation (CCR) in patients with coronary artery disease. The evidence evaluation concluded that "there is limited and very-low quality evidence, which suggests some advantages of ICR over usual care but insufficient evidence to determine whether ICR has advantages compared with conventional cardiac rehabilitation. Most evidence is based on Ornish

programs, and there is an insufficient quantity of data to inform which ICR program, if any, is associated with the best outcomes."

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Cardiac Rehabilitation Programs for Chronic Heart Failure (20.10.1)	2/18/2014
NCD	National	Intensive Cardiac Rehabilitation (ICR) Programs (20.31)	8/12/2010
NCD	National	Benson-Henry Institute Cardiac Wellness Program (20.31.3)	5/6/2014
NCD	National	The Pritikin Program (20.31.1)	8/12/2010
NCD	National	Ornish Program for Reversing Heart Disease (20.31.2)	8/12/2010
LCD		No Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
93797	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)
93798	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)

Considered Not Medically Necessary:

HCPCS Codes	Description
G0422	Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session
G0423	Intensive cardiac rehabilitation; with or without continuous ECG monitoring, without exercise, per session
S9472	Cardiac rehabilitation program, non-physician provider, per diem

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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	• Removed "center-based" from policy statement; removed noncoverage policy statement for virtual/remote home-based and hybrid cardiac rehabilitation.	6/15/2024