Medical Coverage Policy

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Cardiac Rehabilitation (Phase II Outpatient)

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Related Coverage Resources

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Overview

This Coverage Policy addresses cardiac rehabilitation (Phase II) services that are provided on an outpatient basis post facility discharge, including center-based, virtual/remote home-based and hybrid cardiac rehabilitation programs.

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 center-based 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

A virtual/remote home-based or hybrid cardiac rehabilitation program is considered experimental, investigational or unproven.

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)

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 such as valvular heart disease (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 (Thompson, 2019).

- **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 (Wenger, et al., 1995; Thompson, 2019).

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 (Thompson, 2019).

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. 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 patient 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 (Myers and Froelicher, 2013):

- unstable angina
- resting systolic blood pressure >200 mm Hg or diastolic BP >110 mm Hg
- orthostatic blood pressure drop of >20 mm Hg with symptoms
- third-degree heart block (without pacemaker)
- resting ST displacement (>2 mm)
- uncontrolled diabetes
- acute systemic illness or fever
- recent embolism
- active pericarditis or myocarditis
- moderate to severe aortic stenosis
- acute thrombophlebitis
- uncontrolled arrhythmias
- uncompensated congestive heart failure (CHF)
- orthopedic problems that prohibit exercise
- metabolic conditions such as thyroiditis, hypokalemia, hyperkalemia, or hypovolemia

Cardiac Risk Classification
The medically necessary frequency and duration of CR is individualized by assessing the patient's history and current need of cardiac risk factor modification.

Centers for Medicare and Medicaid Services (CMS)
CMS currently covers CR for the following indications (CMS, 2010, 2014):

- 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)

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.

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
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 46 randomized controlled trials in 188,821 patients with coronary artery 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
The American College of Cardiology (ACC) guideline recommendations are classified as Class I, Class IIa, Class IIb, and Class III. The classification system is described as follows:
- Class I: Benefit >>> Risk; Procedure/Treatment should be performed/administered
- Class IIa: Benefit >> Risk; Additional studies with focused objectives needed. It is reasonable to perform procedure/administer treatment.
- Class IIb: Benefit ≥ Risk; Additional studies with broad objectives needed; additional registry data would be helpful. Procedure/treatment may be considered.
- Class III: Risk ≥ Benefit; Procedure/treatment should not be performed/administered, since it is not helpful and may be harmful.

The weight of evidence supporting each recommendation is classified as follows:
- Level A: Multiple populations evaluated. Data derived from multiple randomized clinical trials or meta-analyses.
- Level B: Limited populations evaluated. Data derived from a single randomized trial or nonrandomized studies.
- Level C: Very limited populations evaluated. Only consensus opinion of experts, case studies, or standard of care.

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

The 2013 ACCF/AHA guideline for the management of heart failure recommends that exercise training (or regular physical activity) is safe and effective for patients with heart failure who are able to participate to improve functional status. Class I recommendation with Level of Evidence: A. 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. Class IIa recommendation with Level of Evidence: B (Yancy, et al., 2013). The 2017 focused update to the guideline does not mention cardiac rehabilitation (Yancy, et al., 2017).

The 2014 focused update to the 2007 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 recommendation with Level of Evidence: B) (Amsterdam, et al., 2014)

The 2011 updated ACCF/AHA practice guideline for coronary artery bypass graft (CABG) recommends that CR should be offered to all eligible patients after CABG; Class I recommendation with Level of Evidence: A (Hillis, et al., 2011).

The 2011 ACCF/AHA/Society for Cardiovascular Angiography and Interventions (SCAI) update to the 2005 practice guideline for percutaneous coronary intervention recommends that medically supervised exercise programs (cardiac rehabilitation) be recommended to patients after PCI, particularly for moderate to high-risk patients for whom supervised exercise training is warranted. Class I recommendation with Level of Evidence: A (Levine, et al., 2011).

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 recommendation with Level of Evidence: A).
- All eligible outpatients with the diagnosis of ACS, coronary artery bypass surgery or PCI (Class I recommendation with Level of Evidence: A), chronic angina (Class I recommendation with Level of Evidence: B), and/or peripheral artery disease (Class I recommendation with 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 recommendation with 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 recommendation with Level of Evidence: B) (Smith, et al., 2011)

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 recommendation with Level of Evidence: A). (Fihn, et al., 2012)

The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR)/ACC/AHA 2007 performance measures on CR for referral to CR/secondary prevention services were updated in 2010 and 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 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 cardiac rehabilitation program. The authors noted that improved clinical outcomes are realized with a “full dose” of thirty six 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).

In 2007, the AHA and the 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 which is in agreement with the 2006 AHA/American College of Cardiology (ACC) secondary prevention guidelines, 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.

While virtual, remote, and hybrid CR programs seem to be gaining in popularity in the United States, there are currently no published standards for non-center-based CR. Further, evidence in the peer-reviewed published scientific literature is insufficient to support the safety and long-term efficacy of virtual/remote, home-based and/or hybrid CR programs.

Literature Review
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: 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: 1) age 65 years or older; 2) recent diagnosis of acute coronary syndrome (ACS), coronary revascularization; surgical or percutaneous treatment for valvular disease, and coronary artery disease (CAD), and 3) 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.

Jin et al. (2019) conducted a systematic review and meta-analysis of 32 studies (30 unique randomized controlled trials [RCTs]), to determine whether telehealth (TH) interventions could provide effective secondary prevention as an alternative or adjunct care for patients with coronary heart disease. Telehealth interventions were defined as having greater than 50% of patient–provider contact for risk factor modification instruction delivered via telephone, internet, text messaging, or mobile applications. The comparators included cardiac rehabilitation (CR) or usual care. Cardiac rehabilitation referred to center-based or community-based CR, and usual care was defined as any routine care for coronary heart disease, excluding TH intervention. As an alternative care model, nine studies compared TH interventions with usual care, and two studies compared TH with center-based CR. Telehealth intervention was provided as an adjunct to CR and/or usual care in 21 studies. Among these adjunctive studies, TH intervention began after the completion of CR in seven studies and was an adjunct to usual care in six studies. In eight studies, subjects in both the intervention and control groups could participate in CR during the intervention (however CR participation numbers were only quantified in three trials); and the remaining studies had other varied group allocation and intervention. Trials were conducted between 1994 and 2017. Follow-ups ranged from 3-48 months. In general, TH was not significantly associated with a lower all-cause mortality than CR. TH was significantly associated with lower rehospitalization or cardiac events ($p<0.0001$) compared with non-intervention groups. There was a significantly lower weighted mean difference (WMD) at medium to long-term follow-up than comparison groups for total cholesterol ($p <0.001$), low-density lipoprotein ($p=0.02$) and smoking status ($p=0.04$). Limitations of the review included: heterogeneity in the treatment program regimens, controls, outcome measures, and reporting; small patient populations, lack of detailed data, and varied inclusion/exclusion criteria within the studies.

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 6-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.

Hwang et al. (2017) conducted a blinded, non-inferiority randomized controlled trial (n=53) to determine if small group, home-based telerehabilitation programs for chronic heart failure are inferior to traditional center-based programs, measuring change in six-minute walk distance and other defined outcomes. The control group underwent a traditional, comprehensive center-based heart failure rehab program over 12 weeks. Exercise periods were 60 minutes per session, two sessions per week. The program also included education in home exercises (to be done three times per week), disease self-management, nutritional counseling, physical activity counseling, psychological interventions, medications, and risk factor management. The intervention (home) group received the same exercise program via synchronous, two-way videoconferencing, to groups of up to four participants in the home. Additional educational topics were the same as the control group, delivered via electronic presentations. Participants measured and verbally reported their blood pressure, heart rate, and oxygen saturation each session. Inclusion criteria were: recent hospitalization for heart failure, diagnosis of chronic heart failure, presented with clinical heart failure symptoms, and age over 18 years. Excluded from the study were patients who had symptomatic severe aortic stenosis, significant ischemia at low exercise intensity, lived in an institution (e.g. nursing home), lived more than one hour away from treating hospital, and/or had no support person at home. Outcomes included: six-minute walk distance (in meters), balance, 10-meter walk test time, grip strength, quadriceps strength, urinary incontinence, quality of life, patient satisfaction, program attendance, and adverse events. Follow ups occurred at three months and six months. One subject in the intervention group and three from the control group were lost to follow up. Outcomes reported that there was no statistically significant difference between the groups in six-minute walk distance ($p=0.24$; both groups significantly improved). Non-inferiority was demonstrated at three months' follow up, however non-inferiority to center-based CR could not be proven at the six-month follow up point. Quality of life ratings were significantly improved for both groups, with no statistically significant between-group differences. Attendance was significantly higher for the intervention (home) group (mean difference of 6). There were no significant findings or differences for other outcome measures. There were no reported hospitalizations, deaths, or falls. The intervention group reported three episodes of angina, two episodes of palpitations, and one episode of diaphoresis. The control group reported two episodes of diaphoresis. Author-noted limitations included: possible recruitment bias of an already motivated population; the study was conducted in a metropolitan area with reliable internet coverage

therefore the applicability of telerehabilitation in rural and remote areas with variable internet coverage is unclear; non-block randomization design was used for the study, which resulted in uneven group allocation; and the extent to which participants carried out independent home exercises beyond the formal program sessions was not objectively evaluated, therefore, the exact training volume could not be ascertained. Additional limitations include the small patient population; short-term follow up; underrepresentation of women and non-Caucasians; diagnosis limited to heart failure; and included only low to moderate risk individuals.

A Cochrane systematic review and meta-analysis of 23 randomized controlled trials (n=2,890 participants) by Anderson et al. (2017) 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.

Smolis-Bąk et al. (2015) completed a randomized controlled trial (n=52) to assess the effects of hospital-based and home-based exercise training on exercise capacity in patients with advanced congestive heart failure (CHF) and implanted CRT-D (cardiac resynchronization therapy with defibrillator) devices. Participants underwent cardiopulmonary exercise testing prior to CRT-D implantation and at 3-4 months and 12 months post-implantation. Echocardiography and a six-minute walk test (6-MWT) were performed prior to and 12 months after CRT-D implantation. Both groups completed initial inpatient exercise training for about three weeks. After discharge, the intervention group continued an exercise training program at home with telemonitoring five times a week for eight weeks. The control group did not continue a training program after hospital discharge. Inclusion criteria were: CHF diagnosis; New York Heart Association (NYHA) class III; left ventricular ejection fraction (EF) < 35%; planned implantation of a CRT-D device; controlled hypertension, diabetes and/or other metabolic disorders; capacity to perform treadmill exercise test; and the absence of complex arrhythmia. Exclusion criteria

included: acute/uncontrolled disorders other than CHF and severe mobility impairment, severe musculoskeletal conditions which preclude physical rehabilitation, planned cardiac surgery or percutaneous coronary interventions (PCIs), cardiac surgery or coronary angioplasty within the prior three months, acute coronary syndrome, stroke or transient ischemic attack within the prior six months, history of venous thrombosis or pulmonary embolism, or significant valve and pulmonary diseases. The outcomes analyzed were: peak oxygen uptake (VO_2 peak), peak carbon dioxide output (VCO_2 peak), six-minute walk test (6MWT), anaerobic threshold (AT), exercise tolerance (as per metabolic equivalents [METs] and treadmill test duration), echocardiography, depression, and quality of life. Points of follow up were three to four months, 12 months, and 18 months (adverse events data only). Loss to follow up was not reported. At the initial 3-4 month follow up, the intervention group had improved outcomes in VO_2 peak, VCO_2 peak, and treadmill test duration (p=0.0324; p=0.0059; and p=0.0076, respectively), as compared to the control group. These measures, along with METs, improved significantly in subjects from both groups. At 12 months, the improvement in most of these measurements was maintained in the control group only while in the intervention group the measurements returned to baseline values. There were no significant between-group differences in other measures or at other points of follow up. At the 18-month follow up, no significant between-group differences were noted in mortality or hospitalization rates. Author-noted limitations of the study included single-center study, small patient population, low intensity of the home exercise program, and relatively short duration of the program. Additional limitations noted are that the control group was significantly older than the intervention group (p=0.0192), the limited nature of inclusion and exclusion criteria, the unknown impact of the CRT-D implantation, and the use of routine follow up as opposed to center-based CR as the control.

Lear et al. (2014) completed a randomized controlled trial (n=78) to test the effectiveness of a virtual cardiac rehabilitation program (vCRP) delivered via the Internet. The 16-week proprietary web-based program provided participants with an exercise prescription, tasks, one-on-one chat sessions with staff, peer-support group chat sessions, ask-an-expert chat sessions, health topic education, and progress reports. Subjects in the control group received standard care from their primary care physician, simple guidelines for safe exercising and healthy eating habits, and a list of Internet-based resources. Included in the study were low to moderate risk patients who had a recent hospitalization for either acute coronary syndrome or a revascularization procedure, had regular Internet access, and had no limitations to regular physical activity. Excluded from the trial were patients with previous cardiac rehabilitation experience, depression, uncontrolled diabetes or other significant comorbidities, and pregnant women. Outcome measures were exercise capacity (per symptom-limited maximal treadmill exercise test), cholesterol markers, blood glucose, blood pressure, smoking status, body mass index, weight, waist circumference, leisure time physical activity (LTPA), diet, hospital admissions, and emergency room visits. Follow ups were conducted at four and 16 months; loss to follow up was 9%. Subjects in the vCRP group had a greater increase in maximal time on the treadmill by 45.7 seconds as compared with the control group during the 16 months (p=0.045). The vCRP group also had significantly lower dietary saturated fat (p=0.03) and higher protein intake (p=0.018) versus the usual care group. There was a non-significantly greater number of unique patients with ≥1 ER visit or major event in the control group as compared with the vCRP group (30% vs 18%). There were no significant differences in other outcome measures. Limitations of the trial included: small patient population, an underrepresentation of women, inability to perform a VO_2 assessment, lack of four-month follow up data analysis, and incomplete data from patient-initiated uploads.

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. It is estimated that less than 20% of eligible patients enroll in CR after a qualifying event. Participation is particularly low among women, veterans, Medicare beneficiaries, older adults, and individuals from underserved populations. 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).

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 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 (updated 2020) Comparative Effectiveness Review 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.”

Use Outside of the US
The European Association for Cardiovascular Prevention and Rehabilitation, The American Association of Cardiovascular and Pulmonary Rehabilitation, and The Canadian Association of Cardiac Rehabilitation joint position statement on Aerobic Exercise Intensity Assessment and Prescription in Cardiac Rehabilitation concludes that “In current cardiac rehabilitation practice, the choice of the aerobic training stimulus intensity in individual patients remains largely a matter of clinical judgment. This European, US and Canadian joint position statement provides evidence-based indications for a shift from a ‘range-based’ to a ‘threshold-based’ aerobic

exercise intensity prescription, to be combined with thorough clinical evaluation and exercise-related risk assessment. The importance of functional evaluation through exercise testing prior to starting an aerobic training program is strongly emphasized, and an incremental cardiopulmonary exercise test, when available, is proposed as the gold standard for a physiologically comprehensive exercise intensity assessment and prescription. This would allow professionals to match the unique physiological responses of different exercise intensity domains to the individual patient pathophysiological and clinical status, maximizing the benefits obtainable from aerobic exercise training in cardiac rehabilitation" (Mezzani, et al., 2013).

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Cardiac Rehabilitation Programs (20.10)	2/22/2010
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)	8/15/2010
LCD		No Local Coverage Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
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)

†Note: A virtual/remote home-based or hybrid cardiac rehabilitation program is considered experimental, investigational or unproven.

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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