Clinical Review Criteria
Cardiac Rehabilitation

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Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
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<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>Medicare Pub 100-03 – Cardiac Rehabilitation Programs</td>
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<td></td>
<td>Medicare Claims Processing Manual Chapter 32, Section 140</td>
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<td></td>
<td>Medicare National Coverage Determinations Manual Chapter 1, Part 1 (Sections 10 – 80.12)</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
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<td>Local Coverage Determinations (LCD)</td>
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<tr>
<td>Local Coverage Article</td>
<td>Outpatient Cardiac Rehabilitation A54070</td>
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For Non-Medicare Members

Kaiser Permanente has elected to use the Cardiac Rehabilitation (KP-0358) MCG* for medical necessity determinations.

*MCG Manuals are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:
- Last 6 months of cardiology notes

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Cardiovascular disease (CVD) is the most common cause of office visits, hospitalizations, and deaths in the United States. In recent years, there has been great progress in pharmacological therapies as well as technology-based diagnostic and therapeutic interventions for CVD. As a consequence, a greater number of patients survive acute events, but with a heavier burden of chronic conditions and clinical needs. In addition to medication and interventional cardiology, these patients also need structured support to restore their quality of life and to maintain or improve functional capacity.

Cardiac rehabilitation (CR) was initially developed in response to the profound deconditioning caused by the prolonged bed rest that was common in the management of patients following acute cardiac events in the first half of the 20th century. Since then it has developed into multidisciplinary programs to optimize the health of patients with an expanding range of cardiovascular disease (Gordon 2010). CR is a multifactorial, comprehensive intervention defined as the coordinated sum of interventions required to ensure the best physical, psychological, and social conditions so that patients with chronic or post-acute CVD event may, by their own efforts, preserve or resume optimal functioning in society, and through improved health behaviors, slow or reverse progression of disease (Taylor 2004). It is also viewed as the clinical application of preventive care by means of a professional
multi-disciplinary integrated approach for comprehensive risk reduction and global long-term care of cardiac patients (Piepoli 2010).

The American Heart Association (AHA), the American College of Cardiology (ACC), and the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) consider cardiac rehabilitation / secondary prevention programs integral to the comprehensive care of patients with CVD. They recommend that all cardiac rehabilitation/secondary prevention programs should contain specific core components that aim at optimizing cardiovascular risk reduction, foster healthy behaviors and compliance with these behaviors, reduce disability, and promote an active lifestyle for patients with cardiovascular disease. The core components include baseline patient assessment, nutritional counseling, risk factor management (weight, blood pressure, lipids, diabetes mellitus and smoking), psychological interventions, physical activity counseling, and exercise training (Balady 2007). The goals of CR consist primarily of mobilizing the patient, optimizing drug therapy, implementing measures of secondary prevention, providing means for understanding the disease through education and advice, facilitating behavior modification, supporting the patient in overcoming the disease, treating psychological disturbances, and improving reintegration into professional life (Farin 2007). It is clearly understood and accepted that an isolated exercise program is not cardiac rehabilitation; however, physical activity and exercise training are considered the core components on which a comprehensive CR program is built (Piepoli 2010).

Most CR programs are held for groups in hospitals, gyms, or community centers. These may be inconvenient to patients (especially women and older patients) who may have problems with accessibility, dislike of groups, and/or work on domestic commitments. Home-based programs were thus introduced as an alternative to traditional CR in an attempt to increase participation rates. These programs have been defined as structured programs with clear objectives to the participants, including monitoring, follow-up, visits, letters, telephone calls from staff, or at least self-monitoring diaries (Dalal 2010).

Medical Technology Assessment Committee (MTAC)

Cardiac Rehabilitation

12/20/2010: MTAC REVIEW

Evidence Conclusion: The majority of the studies on cardiac rehabilitation for heart failure or stable MI were small trials, with short follow-up duration, and mainly examined the safety and efficacy of exercise-based programs. The CR programs undergone in the trials differed in their duration (range 1-6 months), frequency (1-5 sessions per week), and session length (20-60 minute /session), and most exercise programs and rehabilitation interventions were tailored on the individual patient’s needs. Several meta-analyses were thus conducted to pool the results of these trials to provide sufficient power to adequately address the effect of comprehensive CR programs on morbidity, mortality, HRQoL, and modifiable risk factors. Cardiac rehabilitation programs for patients with CHD: Several earlier meta-analyses examined the effects of exercise based cardiac rehabilitation on patients with MI and found a survival benefit of the programs. The latest of these meta-analyses was performed by Taylor and colleagues (2004) and included 48 trials with 8,840 participants. Most studies recruited patients at low risk of another event after an MI. The exercise program, as well as the duration of follow-up varied widely between studies. The results of the pooled analysis showed that, compared with usual care, CR reduced total mortality by 20% and cardiac mortality by 26%. There were also significant reductions in some modifiable risk factors including total cholesterol, triglycerides, systolic blood pressure, and smoking. There were no statistically significant reductions in the rate of recurrent MI or revascularization. The main analysis combined the results of exercise only trials with studies on comprehensive cardiac rehabilitation. A subgroup analysis performed by the authors showed a significant mortality benefit with comprehensive CR programs. A decrease in total and cardiac mortality with CR may be due at least in part, to the serial surveillance provided by the rehabilitation staff, which may lead to the detection of any deterioration in the clinical status before it progresses to a more morbid condition or event.

Cardiac rehabilitation programs for patients with heart failure: Davies et al’s Cochrane review in 2010, on the effect of exercise training in patients with systolic heart failure showed that exercise training reduces heart-failure related hospital admission and improves HRQoL in patients who were mainly men with a mean age ranging from 43-72 years, and with NYHA class II-III systolic HF. No effect on mortality was observed. All studies included in the analysis, except for one relatively small (N=200) trial, were exercise only interventions. The analysis included the HF-ACTION study which was a large trial (N=2,331) on the effect of exercise training on HF patients. CR programs aim at enhancing self-management and are not restricted to exercise but should also include education, risk factor management, pharmacological therapies, and psychological input. An earlier meta-analysis (van Tol 2006 ), evaluating the effect of exercise training on cardiac performance in 35 RCTs including 1,486 patients with stable mild to moderate CHF showed that exercise training leads to significant improvements in cardiac performance and quality of life. The meta-analysis did not study the effect on mortality or rate of hospitalization due to HF. Austin et al, 2008, reported on long term results of a trial that randomized 200 patients over 60 years of age with LV systolic dysfunction NYHA class II-III, to receive either standard care or undergo a comprehensive CR program for 24 weeks. Five-year follow up of 56% of the patients showed some long- term benefit on the
functional performance and perceived exertion of the patients. In a more recent small study that included older HF patients, and HF patients with normal ejection fraction, Davidson and colleagues (2010) showed that a multidisciplinary heart failure CR program significantly reduced hospital admission rates due to a cardiovascular or any other event. Home-based versus center-based cardiac rehabilitation for patients with coronary heart disease: A large number of trials compared the outcome of home versus center-based CR on patients with CVD. The majority of trials were small in size with the exception of a more recent trial (Birmingham Rehabilitation Uptake Maximization [BRUM]), which included 525 participants after experiencing an acute MI or coronary revascularization. The results of this trial found no difference in risk factor control or self-reported physical activity between patients randomized to home versus center-based CR. The study was not designed as an equivalence trial, and a lack of significant difference between the two strategies does necessarily indicate that they have similar effects. A recent Cochrane review (Dalal 2010) pooled the results of the 12 RCTs involving almost 1200 participants in total. The trials excluded high risk patients (those with arrhythmias or severe ischemia) and only 2 studies included HF patients. The patient characteristics as well as duration, frequency, and session lengths of CR programs varied widely between studies, and several of the home-based programs started with center-based CR then transitioned to CR at home. The results of the analyses showed no significant differences between the home versus center-based CR programs in risk factors control, HRQoL measures, and all cause mortality. The authors concluded that home-based and center-based CR programs appear to be equally effective in improving clinical and health related QOL outcomes in patients with low risk after MI or revascularization. The results may suggest that the outcomes between home-based and center-based CR are similar, however lack of significant differences does not necessarily imply that the two strategies are equally effective.

Conclusion: There is fair evidence that exercise-based cardiac rehabilitation programs reduces mortality, morbidity, and improves health related quality of life (HRQoL), and modifiable risk factors in low risk patients with coronary heart disease. There is fair evidence that exercise-based cardiac rehabilitation programs reduce hospital admission and improves HRQoL among low- to moderate- risk patients with stable heart failure. There is inconclusive evidence that home-based and center-based CR have similar benefits. The results of trials and meta-analyses comparing the two strategies suggest that they have similar outcomes. However, due to the study designs, a lack of significant statistical differences in the outcomes does not necessarily imply that the two strategies are equivalent.

Articles: The literature search revealed at least 15 meta-analyses on cardiac rehabilitation, and a large number of randomized controlled trials, and observational studies. The great majority of the meta-analyses and trials were performed on individual components of the cardiac rehabilitation (CR) program, mainly exercise-based programs, in stable patients post myocardial infarction or coronary revascularization, or in patients with heart failure. Overall, the randomized trials on the comprehensive CR were relatively small and with short duration of follow-up. One trial (Austin 2008), reported on 5 years outcome of patients with heart failure after undergoing a multidisciplinary 8-week CR program. The literature search also revealed 4 recent meta-analyses of RCTs that compared home-based cardiac rehabilitation versus center-based programs for patients with cardiovascular disease. Studies (e.g. HF-ACTION) or meta-analyses (e.g. ExTraMATCH) that examined the safety and efficacy of exercise training or other single components of the program in patients with chronic heart failure or CAD were not included in the current review which evaluates the multidisciplinary cardiac rehabilitation program. The following meta-analyses of trials on comprehensive CR for patients with heart failure or CHD, that compared and home-based vs. center-based CR as well as the RCT with 5-year follow-up were selected for critical appraisal. Davies EJ, Moxham T, Rees K, et al. Exercise training for systolic heart failure: Cochrane systemic review and meta-analysis. Eur J Heart Fail 2010;12:706-715. See Evidence Table. Davidson PM, Cockburn J, Newton PJ, et al. Can a heart specific cardiac rehabilitation program decrease hospitalization and improve outcomes in high-risk patients? Eur J Cardiovasc Prev Rehabil 2010;17:393-402. See Evidence Table. Taylor RS, Brown A, Ebrahim S, et al. Exercise-based rehabilitation for patients with coronary heart disease: Systematic review and meta-analysis of randomized controlled trials. Am J Med 2004;116:682-692. See Evidence Table. Austin J, Williams WR, Ross L, et al. Five year follow-up findings from randomized trials of cardiac rehabilitation for heart failure. Eur J Cardiovasc Prev Rehabil 2008;15:162-167. See Evidence Table. Dalal HM, Zawada A, Jolly K, et al. Home based versus center based cardiac rehabilitation: Cochrane systemic review and meta-analysis. BMJ 2010;340:C1133. See Evidence Table.

The use of cardiac rehabilitation facility and home based does not meet the Kaiser Permanente Medical Technology Assessment Criteria.
### MPC Medical Policy Committee

<table>
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<tr>
<th>Revision History</th>
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<tr>
<td>06/10/2015</td>
<td>Link for Medicare Pub 100-03 Cardiac Rehabilitation added</td>
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<tr>
<td>09/27/2016</td>
<td>Added NCD 20.31.3 and NCD 20.10.1</td>
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**Codes**

CPT: 93797, 93798, G0422, G0423, S9472