

(80308)

Medical Benefit		Effective Date: 01/01/17	Next Review Date: 05/18
Preauthorization	No	Review Dates: 07/07, 07/08, 05/09, 05/10, 05/11, 05/12, 05/13, 05/14, 09/14, 09/15, 09/16, 05/17	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With diagnosed heart disease 	Interventions of interest are: <ul style="list-style-type: none"> Outpatient cardiac rehabilitation 	Comparators of interest are: <ul style="list-style-type: none"> Standard management without cardiac rehabilitation 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Disease-specific survival Symptoms Morbid events
Individuals: <ul style="list-style-type: none"> With diagnosed heart disease without a second event 	Interventions of interest are: <ul style="list-style-type: none"> Repeat outpatient cardiac rehabilitation 	Comparators of interest are: <ul style="list-style-type: none"> Single course of outpatient cardiac rehabilitation 	Relevant outcomes include: <ul style="list-style-type: none"> Overall survival Disease-specific survival Symptoms Morbid events

Description

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

Summary of Evidence

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

The evidence for repeat outpatient cardiac rehabilitation in individuals who have diagnosed heart disease without a second event includes limited research. Relevant outcomes are overall survival, disease-specific survival, symptoms, and morbid events. No studies were identified that evaluated the effectiveness of repeat

participation in a cardiac rehabilitation program. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

Outpatient cardiac rehabilitation programs are considered **medically necessary** for patients with a history of the following conditions and procedures:

- acute myocardial infarction (MI) (heart attack) within the preceding 12 months;
- coronary artery bypass graft (CABG) surgery;
- percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting;
- heart valve surgery;
- heart or heart-lung transplantation;
- current stable angina pectoris; or
- compensated heart failure.

Repeat participation in an outpatient cardiac rehabilitation program in the absence of another qualifying cardiac event is considered **investigational**.

Policy Guidelines

The following components must be included in cardiac rehabilitation programs:

- Physician-prescribed exercise each day cardiac rehabilitation services are provided;
- Cardiac risk factor modification;
- Psychosocial assessment;
- Outcomes assessment; and
- Individualized treatment plan detailing how each of the above components are utilized.

A standard of care cardiac rehabilitation exercise program may involve three sessions per week up to a 12-week period (36 sessions). Programs should start within 90 days of the cardiac event and be completed within six months of the cardiac event.

A comprehensive evaluation may be performed before initiation of cardiac rehabilitation to evaluate the patient and determine an appropriate exercise program. In addition to a medical examination, an electrocardiogram stress test may be performed. An additional stress test may be performed at the completion of the program.

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

Note: For general business this protocol does not address Intensive Cardiac Rehabilitation Programs, such as the Dean Ornish Program for Reversing Heart Disease, the Pritikin Program and the Benson-Henry Institute Cardiac Wellness Program.

Medicare Advantage

Outpatient cardiac rehabilitation (CR) and intensive cardiac rehabilitation (ICR) are considered **medically necessary** program services for patients who have experienced one or more of the following:

- An acute myocardial infarction within the preceding 12 months; or
- A coronary artery bypass surgery; or
- Current stable angina pectoris; or
- Heart valve repair or replacement; or
- Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; or
- A heart or heart-lung transplant; or
- Stable, chronic heart failure* (see Medicare Advantage Policy Guidelines)

See Medicare Advantage Policy Guidelines for approved programs for ICR.

Medicare Advantage Policy Guidelines

*Stable, chronic heart failure is defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least six weeks. Stable patients are defined as patients who have not had recent (less than or equal to six weeks) or planned (less than or equal to six months) major cardiovascular hospitalizations or procedures.

Intensive cardiac rehabilitation refers to a physician-supervised program that furnishes cardiac rehabilitation services more frequently and often in a more rigorous manner.

Medicare will publish a list of approved programs for ICR in the Federal Register. Available at <https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/ICR.html>. A copy of Medicare's approval must be available at our request and filed in the patient's medical records.

Background

Heart disease is the leading cause of mortality in the United States, causing more than half of all deaths. Coronary artery disease (CAD) is the most common cause of heart disease. In the most recently updated (2015) report on heart disease and stroke statistics from the American Heart Association, it was estimated that an estimated 635,000 Americans have a new coronary attack (first hospitalized myocardial infarction or coronary heart disease death) and 300,000 have a recurrent attack annually.¹ Both CAD and various other disorders—structural heart disease and other genetic, metabolic, endocrine, toxic, inflammatory, and infectious causes—can lead to the clinical syndrome of heart failure, of which there are about 650,000 new cases in the U.S. annually.² Given the burden of heart disease, preventing secondary cardiac events and treating the symptoms of heart disease and heart failure have received much attention from national organizations.

In 1995, the U.S. Public Health Service (USPHS) defined cardiac rehabilitation services as, in part, “comprehensive, long-term programs involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling.... [These programs are] designed to limit the physiologic and psychological effects of cardiac illness, reduce the risk for sudden death or reinfarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the psychosocial and vocational status of selected patients.” This USPHS guideline recommended cardiac rehabilitation services for patients with coronary heart disease and with heart failure, including those awaiting or following cardiac transplantation. A 2010 definition of cardiac rehabi-

litation by the Cardiac Rehabilitation Section of the European Association of Cardiovascular Prevention and Rehabilitation is as follows: “Cardiac rehabilitation can be viewed as the clinical application of preventive care by means of a professional multi-disciplinary integrated approach for comprehensive risk reduction and global long-term care of cardiac patients.”³ Since release of the USPHS guideline, other societies, including the American Heart Association⁴ and the Heart Failure Society of America⁵ have developed guidelines about the role of cardiac rehabilitation in patient care.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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