Protocol

Cardiac Rehabilitation in the Outpatient Setting

(80308)

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

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required.*** *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.*

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 recently specified core components to be included in cardiac rehabilitation programs.

Background

Heart disease is the leading cause of mortality in the U.S., causing more than half of all deaths. Coronary artery disease (CAD) is the most common cause of heart disease. Annually, it is estimated that 785,000 Americans suffer a new myocardial infarction (MI), and 470,000 have a recurrent MI. (1) In addition, CAD can lead to the clinical syndrome of heart failure, which occurs in about 650,000 new cases in the U.S. annually. (2) Heart failure may be secondary to or coexist with to CAD, but can also be related to structural heart disease and other genetic, metabolic, endocrine, toxic, inflammatory, and infectious causes. Given the disease 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." (3) 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 rehabilitation 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." (4) Since the release of the USPHS guideline, other societies, including the American Heart Association (5) and the Heart Failure Society of America (6) have developed guidelines about the role of cardiac rehabilitation in patient care.

Note: This Protocol description does not address programs considered to be "Intensive Cardiac Rehabilitation Programs," such as the Dean Ornish Program for Reversing Heart Disease and the Pritikin Program.

Policy (Formerly Corporate Medical Guideline)

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 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 prior to 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: Contract language regarding session limits may be applicable. For general business this Protocol does not address programs considered “Intensive Cardiac Rehabilitation Programs,” such as the Dean Ornish Program for Reversing Heart Disease and the Pritikin 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, 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 (≤ six weeks) or planned (≤ six months) major cardiovascular hospitalizations or procedures.

Cardiac rehabilitation programs (CR and ICR) must include the following components:

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

Cardiac rehabilitation items and services must be furnished in a physician's office or a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all time items and services are being furnished under the program.

Cardiac rehabilitation (CR) may be **medically necessary** a maximum of two one-hour sessions per day. Each session must be at least 31 minutes and two sessions must be at least a total of 91 minutes. Cardiac rehabilitation program sessions are limited to a maximum of two one-hour sessions per day for up to 36 sessions over or up to 36 weeks, with the option for an additional 36 sessions over an extended period of time if medically necessary.

For ICR to be considered **medically necessary** it must be provided only through programs approved by original Medicare through the NCD process (National Coverage Determination process). In order to be considered for their approval, a program must demonstrate through peer-reviewed published research that it has accomplished one or more of the following for its patients:

- Positively affected the progression of coronary heart disease;
- Reduced the need for coronary bypass surgery; and
- Reduced the need for percutaneous coronary interventions.

An intensive cardiac rehabilitation program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in five or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services:

- Low density lipoprotein;
- Triglycerides;
- Body mass index;
- Systolic blood pressure;
- Diastolic blood pressure; and
- The need for cholesterol, blood pressure, and diabetes medications.

Intensive cardiac rehabilitation items and services must be furnished in a physician's office or a hospital outpatient setting. All settings must have a physician immediately available and accessible for medical consultations and emergencies at all time items and services are being furnished under the program. Intensive

cardiac rehabilitation may be medically necessary a maximum of six one-hour sessions per day. Each session must be at least 31 minutes and the maximum six sessions must be at least a total of 331 minutes. Intensive cardiac rehabilitation program sessions are limited to 72 one-hour sessions, up to six sessions per day, over a period of up to 18 weeks.

Medicare will publish a list of approved programs in the Federal Register. A copy of Medicare's approval must be available at our request and filed in the patients medical records.

At this time there are CMS NCDs that indicate the following are approved programs for intensive cardiac rehabilitation:

- The Pritikin Program
- Ornish Program for Reversing Heart Disease.

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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17. Medicare Claims Processing Manual Publication 100-04 Chapter 32. Available online at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads//clm104c32.pdf. Last accessed May, 2014.
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