

Protocol

Cardiac Rehabilitation in the Outpatient Setting

(80308)

Medical Benefit		Effective Date: 07/01/18	Next Review Date: 05/21
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, 05/18, 05/19, 05/20	

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: • With diagnosed heart disease	Interventions of interest are: • Outpatient cardiac rehabilitation	Comparators of interest are: • Standard management without cardiac rehabilitation	Relevant outcomes include: • Overall survival • Disease-specific survival • Symptoms • Morbid events
Individuals: • With diagnosed heart disease without a second event	Interventions of interest are: • Repeat outpatient cardiac rehabilitation	Comparators of interest are: • Single course of outpatient cardiac rehabilitation	Relevant outcomes include: • Overall survival • Disease-specific survival • Symptoms • Morbid events
Individuals: • With diagnosed heart disease	Interventions of interest are: • Intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease	Comparators of interest are: • Standard outpatient cardiac rehabilitation	Relevant outcomes include: • Overall survival • Disease-specific survival • Symptoms • Morbid events
Individuals: • With diagnosed heart disease	Interventions of interest are: • Intensive cardiac rehabilitation with the Pritikin Program	Comparators of interest are: • Standard outpatient cardiac rehabilitation	Relevant outcomes include: • 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

For individuals who have diagnosed heart disease who receive outpatient cardiac rehabilitation, the evidence includes multiple randomized controlled trials (RCTs) 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 select patients, particularly those with coronary heart disease, heart failure, and who have had cardiac surgical interventions. 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 that the technology results in a meaningful improvement in the net health outcome.

For individuals who have diagnosed heart disease without a second event who receive repeat outpatient cardiac rehabilitation, the evidence includes no trials. Relevant outcomes are overall survival, disease-specific survival, symptoms, and morbid events. No studies were identified evaluating the effectiveness of repeat participation in a cardiac rehabilitation program. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have diagnosed heart disease who receive intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease, the evidence includes an RCT and uncontrolled studies. Relevant outcomes are overall survival, disease-specific survival, symptoms, and morbid events. No RCTs have compared the Ornish Program with a “standard” cardiac rehabilitation program; an RCT compared it with usual care. The trial included patients with coronary artery disease and no recent cardiac events and had mixed findings at one and five years. The trial had a small sample size for a cardiac trial (N=48), and only 35 patients were available for the five-year follow-up. The Ornish Program is considered by the Centers for Medicare & Medicaid Services as an intensive cardiac rehabilitation program, but the program described in the RCT could meet criteria for standard cardiac rehabilitation. No studies were identified comparing the Ornish Program with any other cardiac rehabilitation program. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have diagnosed heart disease who receive intensive cardiac rehabilitation with the Pritikin Program, the evidence includes a case series. Relevant outcomes are overall survival, disease-specific survival, symptoms, and morbid events. Studies are needed that compare the impact of intensive cardiac rehabilitation using the Pritikin Program with standard outpatient cardiac rehabilitation programs. 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 (heart attack) within the preceding 12 months;
- coronary artery bypass graft surgery;
- percutaneous transluminal coronary angioplasty 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**.

Intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease or Pritikin Program 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 is eligible for coverage for 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.

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

Heart disease is the leading cause of mortality in the United States, accounting for more than half of all deaths. Coronary artery disease is the most common cause of heart disease. In a 2015 update on heart disease and stroke statistics from the American Heart Association, it was estimated that 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 coronary artery disease 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.

Cardiac Rehabilitation

In 1995, the U.S. Public Health Service 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.” The U.S. Public Health Service 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 from the European Association of Cardiovascular Prevention and Rehabilitation stated: “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.”² Since the release of the U.S. Public Health Service guidelines, other societies, including the American Heart Association (2005)³ and the Heart Failure Society of America (2010)⁴ have developed guidelines on the role of cardiac rehabilitation in patient care.

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