Cardiac Rehabilitation in the Outpatient Setting

Policy # 00570
Original Effective Date: 09/20/2017
Current Effective Date: 09/19/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider outpatient cardiac rehabilitation programs for patients with a history of the following conditions and procedures to be **eligible for coverage:**

- 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.

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 3 sessions per week up to a 12-week period (36 sessions). Programs should start within 90 days of the cardiac event (with exception of acute myocardial infarction as noted above) and be completed within 6 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.

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When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers cardiac rehabilitation in the outpatient setting when criteria are not met to be **investigational.***

Based on review of available data, the Company considers repeat participation in an outpatient cardiac rehabilitation program in the absence of another qualifying cardiac event to be **investigational.***

Based on review of available data, the Company considers intensive cardiac rehabilitation with the Ornish Program for Reversing Heart Disease or Pritikin Program to be **investigational.***

Background/Overview

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 (CAD) 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. 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. 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 (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 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." Since release of the USPHS guideline, other societies, including the American Heart Association (2005) and the Heart Failure Society of America (2010) have developed guidelines on the role of cardiac rehabilitation in patient care.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Not applicable.

Centers for Medicare and Medicaid Services (CMS)

Cardiac Rehabilitation
Medicare has had a national coverage determination (NCD) for cardiac rehabilitation since 1989. There was a change in Medicare coverage for cardiac rehabilitation in January 2010. Indications for coverage remained the same; namely, patients who have experienced at least one of the following:

- Acute myocardial infarction within the preceding 12 months
- Coronary artery bypass surgery
- Current stable angina pectoris
- Heart valve repair or replacement
- Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting
- Heart or heart-lung transplant

As of February 2014, a change was made to the patient criteria to expand eligibility for cardiac rehabilitation to patients with the following: "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. Stable patients are defined as patients who have not had recent (≤ 6 weeks) or planned (≤ 6 months) major cardiovascular hospitalizations or procedures."

The 2010 criteria specify the required components of cardiac rehabilitation programs. Programs must include all of the following:

- "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."

Also, criteria on the frequency and duration of cardiac rehabilitation services were updated. Beginning in January 2010, the criteria were updated:

> "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….

> …[C]ardiac rehabilitation program sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks, with the option of an additional 36 sessions over an extended period of time if approved by the Medicare contractor."

Intensive Cardiac Rehabilitation
Beginning in January 2010, Medicare added intensive cardiac rehabilitation as a benefit. Intensive cardiac rehabilitation programs must be approved by Medicare on an individual basis.

The national coverage determination described intensive cardiac rehabilitation in the following manner:

> "Intensive cardiac rehabilitation (ICR) refers to a physician-supervised program that furnishes cardiac rehabilitation services more frequently and often in a more rigorous manner. As required by §1861(eee)(4)(A) of the Social Security Act (the Act), an ICR program must show, in peer-reviewed published research, that it accomplished one or more of the following for its patients: (1) positively affected the progression of coronary heart disease; (2) reduced the need for coronary bypass surgery; and, (3) reduced the need for percutaneous coronary interventions. The ICR 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: (1) low density lipoprotein; (2) triglycerides; (3) body mass index; (4) systolic blood pressure; (5) diastolic blood pressure; and, (6) the need for cholesterol, blood pressure, and diabetes medications. Individual ICR programs must be approved through the national coverage determination process to ensure that they demonstrate these accomplishments."

In 2010, Center for Medicare & Medicaid Services also issued 2 decision memos on specific programs. One stated that the Ornish Program for Reversing Heart Disease met the intensive cardiac rehabilitation program requirements and was included on the list of approved intensive cardiac rehabilitation programs. It provided the following description of the Ornish Program: "The Ornish Program for Reversing Heart Disease (also known as the Multisite Cardiac Lifestyle Intervention Program, Multicenter Cardiac Lifestyle Intervention Program and the Lifestyle Heart Trial program) … incorporates comprehensive lifestyle modifications including exercise, a low-fat diet, smoking cessation, stress management training, and group support sessions. Over the years, the Ornish program has been refined but continues to focus on these specific risk factors."

The other stated that the Pritikin Program met program requirements and was included on the list of approved intensive cardiac rehabilitation programs. As described in the decision memo: "The Pritikin program (also known as the Pritikin Longevity Program) evolved into a comprehensive program that is provided in a physician's office and incorporates a specific diet (10%–15% of calories from fat, 15%–20% from protein, 65%–75% from complex carbohydrates), exercise and counseling lasting 21-26 days. An optional residential component is also available for participants."

Rationale/Source

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

OUTPATIENT CARDIAC REHABILITATION FOR HEART DISEASE

Systematic Reviews

Oldridge (2012) identified 6 independent meta-analyses published since 2000 that reported outcomes from 71 RCTs (total N=13824 patients) following cardiac rehabilitation interventions. The RCTs included in the meta-analyses enrolled patients with myocardial infarction (MI), coronary heart disease (CHD), angina, percutaneous coronary intervention, and/or coronary artery bypass graft (CABG). RCTs compared cardiac rehabilitation programs (exercise-only and/or comprehensive rehabilitation) with usual care. Cardiac rehabilitation was associated with a statistically significant ($p<0.05$) reduction in all-cause mortality in 4 of the 5 meta-analyses that reported this outcome. In the pooled analysis, cardiac rehabilitation was associated with an 18.5% mean reduction in all-cause mortality. Also, cardiac rehabilitation was associated with a statistically significant reduction in cardiac mortality in 3 of the 4 meta-analyses that reported disease-specific mortality as an outcome.

Two of the meta-analyses on cardiac rehabilitation was conducted by Cochrane. One included patients with CHD and the other focused on patients with systolic heart failure. Both addressed exercise-based cardiac rehabilitation programs (exercise alone or as part of a comprehensive program). Anderson et al (2016) updated a 2011 Cochrane review addressing exercise-based cardiac rehabilitation for individuals with CHD. Reviewers included RCTs of exercise-based interventions with at least 6 months of follow-up compared with no-exercise controls in patients with MI, CABG, or percutaneous coronary intervention, or with angina pectoris or coronary artery disease. The updated review included 63 RCTs (total N=14,486 individuals), of which 16 trials had been published since the 2011 update. Reviewers reported that the overall risk of bias

was unclear, although the quality of reporting improved with more recent trials. Due to the nature of the intervention, patients were not blinded to treatment group in any of the studies, but 16 (25%) of 62 studies reported details of blinded assessment of study outcomes. In the pooled analysis, cardiac rehabilitation was not significantly associated with overall mortality. However, among 27 studies, cardiac rehabilitation was significantly associated with reduced cardiovascular mortality (292/3850 for cardiac rehabilitation subjects vs 375/3619 for control subjects; relative risk [RR], 0.74; 95% confidence interval [CI], 0.64 to 0.86). Rates of MI, CABG, and percutaneous coronary intervention were not significantly associated with receiving cardiac rehabilitation.

A Cochrane review by Taylor et al (2014) reported on studies assessing cardiac rehabilitation in patients with heart failure. Reviewers included 33 trials (total N=4740 individuals), with 14 studies added with the latest update. One large trial (HF-ACTION) contributed 50% of patients; most other studies were small and single center. The population was predominantly patients with heart failure with reduced ejection fraction and New York Heart Association functional class II and III heart failure. The trials had a moderate risk of bias; many earlier studies (particularly pre-2000) had insufficient detail to permit assessment of the risk of bias. In the 25 studies that reported all-cause mortality up to 12-month follow-up, there was no difference in pooled mortality between groups (RR=0.93; 95% CI, 0.69 to 1.27; p=0.59). For health-related quality of life, most studies reported disease-specific quality of life with the Minnesota Living With Heart Failure questionnaire. Although there was statistical heterogeneity in the differences in Minnesota Living With Heart Failure scores between exercise and control groups, there was a significant improvement in Minnesota Living With Heart Failure scores with exercise in the pooled analysis (mean difference, -5.8; 95% CI, -9.2 to -2.4, p=0.001). Most studies selected for the Cochrane review, including the HF-ACTION trial, were exercise-only interventions; thus, conclusions cannot be drawn from this review about the impact of comprehensive cardiac rehabilitation programs on mortality or hospital admissions in patients with heart failure. Reviewers did not require that studies only include patients with compensated heart failure.

Randomized Controlled Trials

Findings of a large, multicenter RCT from the U.K., which evaluated the effectiveness of cardiac rehabilitation in a “real-life” setting, were published by West et al (2012). Called the Rehabilitation After Myocardial Infarction Trial (RAMIT), the study included patients from 14 centers with established multifactorial cardiac rehabilitation programs (including exercise, education, and counseling), involved more than 1 discipline, and provided an intervention lasting a minimum of 10 hours. A total of 1813 patients were randomized—903 to cardiac rehabilitation and 910 to a control condition. Vital status was obtained at 2 years for 99.9% (all but 1 patient) and at 7 to 9 years for 99.4% of patients. By 2 years, 166 patients had died, 82 in the cardiac rehabilitation group and 84 in the control group. The between-group difference in mortality at 2 years (the primary study outcome) was not statistically significant (RR=0.98; 95% CI, 0.74 to 1.30). After 7 to 9 years, 488 patients had died, 245 in the cardiac rehabilitation group and 243 in the control group (RR=0.99; 95% CI, 0.85 to 1.15). In addition, at 1 year, cardiovascular morbidity did not differ significantly between groups. For a combined end point including death, nonfatal MI, stroke, or revascularization, the RR was 0.96 (95% CI, 0.88 to 1.07). In discussing the study’s negative findings, trialists noted that medical management of heart disease had improved over time, and patients in the

control group might have had better outcomes than in earlier RCTs on this topic. Moreover, an editorial accompanying the publication of the trial's findings emphasized that RAMIT was not an efficacy trial, but rather, a trial evaluating the effectiveness of actual cardiac rehabilitation programs in the U.K. Finally, these results might in part reflect the degree to which clinically based cardiac rehabilitation programs in the U.K. differ from the treatment protocols used in RCTs based in research settings.

A concern raised by the negative findings in the RAMIT trial is that most of the RCTs evaluating cardiac rehabilitation were conducted in an earlier era of heart disease management and might not be relevant to current care. However, RAMIT's results, along with 15 additional RCTs reported since a 2011 Cochrane review, were included in the updated 2016 Cochrane review, which found improvements in cardiovascular mortality associated with exercise-based cardiac rehabilitation.

Pandey et al (2017) evaluated endurance exercise training as part of a cardiac rehabilitation program in a population of heart failure patients stratified by ejection fraction. Participants had heart failure with preserved ejection fraction (HFpEF) or reduced ejection fraction, were 65 years of age or older, and had participated in a 16-week exercise program that intensified from 40% to 50% of heart rate reserve in the first 2 weeks to 60% to 70% over the ensuing weeks as part of a previously published RCT (Kitzman et al [2010]). The primary outcome for assessing change in exercise capacity was percentage change in peak oxygen uptake (VO_2peak) (mL/kg per minute) from baseline to end of exercise training (16-week follow-up). Data on testing from 48 patients (24 reduced ejection fraction, 24 HFpEF) were assessed. HFpEF patients experienced greater improvement in exercise training patients (18.7%) than reduced ejection faction patients (-0.3%; $p<0.001$) as measured by VO_2peak. There was no information on subsequent hospitalizations rates or clinical outcomes such as heart failure progression or mortality. This secondary analysis was used to assert the appropriateness of cardiac rehabilitation in HFpEF patients.

Observational Studies
Sumner et al (2017) published a systematic review of controlled observational studies evaluating cardiac rehabilitation in patients diagnosed with acute MI. Cardiac rehabilitation interventions consisted of structured multicomponent programs that included exercise and at least one of the following: education, information, health behavior change, and psychological or social support. Usual care interventions generally supervised medical interventions, were the control conditions. Ten studies met reviewers' eligibility criteria. In a meta-analysis of 5 studies reporting all-cause mortality (an unadjusted outcome), there was a significantly lower risk of death in the group that received cardiac rehabilitation (odds ratio, 0.25; 95% CI, 0.16 to 0.40). Three studies that reported an adjusted analysis of all-cause mortality also found a significant benefit from cardiac rehabilitation (odds ratio, 0.47; 95% CI, 0.38 to 0.59). Similarly, a meta-analysis of 3 studies reporting cardiac-related mortality (an unadjusted analysis) found a significant benefit from cardiac rehabilitation (odds ratio, 0.21; 95% CI, 0.12 to 0.37). Only 1 study reported an adjusted analysis of cardiac-related mortality, so data could not be pooled.

Nilsson et al (2018) investigated the effect of a 12-week cardiac rehabilitation program with a high-intensity interval exercise component using participant VO_2peak as a measure of improved exercise capacity.

Increased exercise capacity has been shown to improve survival among persons with CHD. The objective of the study was to assess whether this addition to a cardiac rehabilitation program yielded improved long-term results. One hundred thirty-three coronary patients participated in this prospective cohort study and were evaluated at baseline, at the end of the 12-week program, and again at a 15-month follow-up. Additional test measurements included a cardiopulmonary exercise test, body mass index, blood pressure tests, and a quality of life questionnaire. Of the 133 patients, 86 patients had complete information for the 15-month follow-up. Mean VO_2peak improved from a baseline of 31.9 mL/kg/min to 35.9 mL/kg/min ($p<0.001$) at the end of the 12-week program, and to 36.8 mL/kg/min (CI not reported) at 15-month follow-up. Most of the 86 patients reported maintaining an exercise routine. Study limitations included the small sample size, a relatively low-risk male population at baseline, and lack of information on the qualifying event for cardiac rehabilitation. The authors concluded that the cardiac rehabilitation program intervention potentially fostered consistent and beneficial exercise habits as demonstrated by improved VO_2peak.

Section Summary: Outpatient Cardiac Rehabilitation for Heart Disease
Overall, the evidence from RCTs reviewed in well-structured systematic reviews suggests that cardiac rehabilitation is associated with reduced cardiovascular mortality in patients with CHD. Additional RCTs, systematic reviews, and observational studies have evaluated outpatient cardiac rehabilitation in patients with heart failure or in the postintervention setting. An overview of 6 meta-analyses found a statistically significant association between cardiac rehabilitation and all-cause mortality and/or cardiac mortality. The available evidence has limitations, including lack of blinded outcome assessment, but, for the survival-related outcomes of interest, this limitation is less critical.

REPEAT OUTPATIENT CARDIAC REHABILITATION

No studies were identified that evaluated the effectiveness of repeat participation in a cardiac rehabilitation program.

INTENSIVE CARDIAC REHABILITATION FOR HEART DISEASE

There is no standard definition of an intensive cardiac rehabilitation program and, thus, specific programs are reviewed individually. Two programs have been evaluated by Centers for Medicare & Medicaid Services, and we describe the published evidence supporting these programs next. The ideal trial design would be an RCT comparing the impact of intensive cardiac rehabilitation with standard cardiac rehabilitation on health outcomes.

Ornish Program for Reversing Heart Disease
Ornish et al (1990) conducted an RCT, called the Lifestyle Heart Trial, comparing a version of the Ornish Program for Reversing Heart Disease with usual care. Initial results were reported in 1990, and 5-year results in 1998. Eligibility for the trial included diagnosed coronary artery disease, left ventricular ejection fraction greater than 25%, no MI during the previous 6 weeks, no scheduled for CABG, and not taking lipid-lowering medication. Ninety-four eligible patients were randomized to an intervention group (n=53) or a usual care control group (n=43). Final consenting was done after randomization; 28 (53%) of patients

assigned to the intervention group and 20 (43%) assigned to the control group agreed to participate in the trial.

The Lifestyle intervention consisted of recommending a low-fat vegetarian diet and an individualized exercise regimen. Also, patients were taught stress management techniques and were taught to practice them at home for at least an hour a day. Also, twice-weekly group discussions were offered to provide social support. It is not clear how long patients attended these group discussion (ie, the number of weeks or months). As reported by Ornish et al (1990), the mean percentage diameter stenosis decreased from 40% at baseline to 37.8% at 1 year in the intervention group and increased from 42.7% to 46.1% in the control group (p=0.001). The frequency and duration of chest pain did not differ between groups. However, during chest pain episodes, at 1 year, the intervention group reported mean chest pain severity of 1.7 (on a 7-point scale) whereas the mean score in the control group was 2.5 (p<0.001).

Twenty (71%) of 28 patients in the intervention group and 15 (75%) of 20 in the control group completed the 5-year follow-up. The intervention and control groups did not differ significantly in the number of MI events (2 vs 4), CABGs (2 vs 5), or deaths (2 vs 1). However, compared with the control group, the intervention group had significantly fewer percutaneous transluminal coronary angioplasties (8 vs 14, p<0.050) and cardiac hospitalizations (23 vs 44, p<0.001).

Section Summary: Ornish Program for Reversing Heart Disease
One RCT was identified that evaluated the Ornish Program in patients diagnosed with heart disease, and compared it with usual care. This RCT, which included patients with coronary artery disease but no recent cardiac event, had mixed findings at 1 and 5 years. The trial had a small sample size for a cardiac trial (N=48), and only 35 patients were available for the 5-year follow-up. The Ornish Program is considered by Centers for Medicare & Medicaid Services to be an intensive cardiac rehabilitation program, but the program described in this RCT might meet criteria for standard cardiac rehabilitation. No studies were identified that compared the Ornish Program with any other cardiac rehabilitation program.

Pritikin Program
No RCTs evaluating the Pritikin Program were identified. The published evidence on this program consists of case series, and only one (Barnard et al [1983]) included patients with heart disease. (Other case series included patients without heart failure, eg, those with high cholesterol levels.) Sixty-four patients with documented coronary artery disease attended a 26-day residential treatment program between 1976 and 1977. During the program, patients were encouraged to walk for 30 to 45 minutes twice a day, learned how to prepare foods consistent with the Pritikin diet, and attended over 60 hours of group education classes. Serum samples were taken at baseline and the end of the program. Patients were called in March 1980 for a follow-up interview and asked to send in serum samples. At the 3- to 4-year follow-up, 12 (19%) of 64 patients had had bypass surgery, and 4 patients had died. Fifty (81%) patients provided serum samples at follow-up, and the mean cholesterol level (166 mg/dL) was significantly lower than the baseline value (220 mg/dL). The trial was limited in the lack of a control group, especially a group receiving “standard” outpatient cardiac rehabilitation, and long-term mortality outcomes were not reported.

Section Summary: Pritikin Program
No RCTs have evaluated the Pritikin Program; a single case series in patients with heart disease was identified. Conclusions cannot be drawn from this series on the impact of intensive cardiac rehabilitation with the Pritikin Program compared with standard outpatient cardiac rehabilitation.

SUMMARY OF EVIDENCE
For individuals who have diagnosed heart disease who receive outpatient cardiac rehabilitation, the evidence includes multiple 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 1 and 5 years. The trial had a small sample size for a cardiac trial (N=48), and only 35 patients were available for the 5-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.

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Policy History

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Current Effective Date: 09/19/2018
09/07/2017 Medical Policy Committee review
09/20/2017 Medical Policy Implementation Committee approval. New policy.
09/06/2018 Medical Policy Committee review
09/19/2018 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 09/2019

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	93797, 93798
HCPCS	G0422, G0423, S9472
ICD-10 Diagnosis	I20.8-I20.9, I21.01-I21.4, I50.1-I50.9, Z94.1, Z94.3, Z95.1-Z95.5, Z98.61

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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