

BSC8.01 Lifestyle Modification Program for Reversing Heart Disease			
Original Policy Date:	November 26, 2014	Effective Date:	May 1, 2023
Section:	8.0 Therapy	Page:	Page 1 of 11

## Policy Statement

- I. Intensive cardiac rehabilitation (ICR, i.e., Dr. Dean Ornish Program for Reversing Heart Disease) may be considered **medically necessary** in individuals when **both** of the following are met:
  - A. Non-smoker or have quit smoking at least 3 months prior to enrolling in program
  - B. Have experienced **one or more** of the following conditions:
    1. Acute myocardial infarction (MI) within the preceding 12 months
    2. Coronary artery bypass surgery
    3. Current stable angina pectoris
    4. Heart or heart-lung transplant
    5. Heart valve repair or replacement
    6. Percutaneous transluminal coronary angioplasty or coronary stenting

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

The program is limited to once per lifetime and prospective participants should be motivated to complete the program and make the necessary lifestyle changes. Due to the comprehensive lifestyle changes required, insufficiently motivated individuals are not recommended as candidates for the Ornish program. Individuals must go through a preliminary screening process prior to acceptance into the program, which is offered by the licensed Ornish provider and ensures that the individual is sufficiently motivated and meets the eligible criteria. Acceptance into the program for a particular individual is at the sole discretion of the applicable Ornish provider.

Intensive cardiac rehabilitation (ICR) programs are limited to 72 one-hour sessions, up to 6 sessions per day, over a period of up to 18 weeks.<sup>1</sup>

\*As of 2023, below are the facilities in California that offer this program:

- Marin Health (Larkspur)
- UCLA Health (Los Angeles)

\*<https://www.ornish.com/ornish-certified-site-directory/>

### Coding

- **G0422:** Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session
- **G0423:** Intensive cardiac rehabilitation; with or without continuous ECG monitoring; without exercise, per session
- **S9472:** Cardiac rehabilitation program, nonphysician provider, per diem

## Description

The Dr. Dean Ornish Program for Reversing Heart Disease is a multifaceted program addressing the well-being of both the body and the mind. By concentrating on four main components (healthy eating, moderate exercise, stress management, and emotional support) including smoking prevention/cessation, it is proposed that heart disease can be prevented, slowed, and even reversed.

The program is considered to be an Intensive cardiac rehabilitation (ICR) program and proposed as a non-surgical alternative for the treatment of coronary artery disease.

### Related Policies

- N/A

### Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

### Regulatory Status

- N/A

### Rationale

#### Background

According to the Centers for Disease Control and Prevention (CDC), about 697,000 people die of heart disease every year in the United States and it is the leading cause of death for both men and women.<sup>2</sup> By targeting HDL/LDL/total cholesterol, blood sugar, blood pressure, and weight for example, the risk for heart disease is lessened. Programs have evolved to target this disease and the associated risk factors. Intensive cardiac rehabilitation (ICR) is a multi-dimensional program incorporating many aspects of well-being, which focus on reducing heart disease risk factors. The Dr. Dean Ornish Program for Reversing Heart Disease is a 72 hour outpatient ICR program (completed in one hour sessions) and is proposed as an alternative to surgical treatment in patients with heart disease. The focus of the Ornish program is to target four components which are thought to slow, stop, and even reverse the progression of coronary artery disease. The four components along with smoking cessation are: low-fat, whole food nutrition; stress management; monitored fitness; and group support. For patients enrolled in the program, there is a team of medical professionals assigned to their treatment (i.e., physician/ medical director, nurse case manager, exercise physiologist, clinical psychologist, registered stress management instructor, and a registered dietician). The program focuses on lifestyle changes versus the use of medications and surgery to treat and prevent coronary artery disease. The clinical outcomes of the program are improvements in blood pressure, weight, body mass index, cholesterol, angina, depression, hostility, and vitality.<sup>3</sup>

Dr. Dean Ornish is the founder of the nonprofit Preventive Medicine Research Institute (PMRI) and has been conducting research for over 30 years on how diet and lifestyle can affect health and overall well-being. The following is a review of the literature which focuses on the effects of life-style changes as treatment/prevention for heart disease.

## Literature Review

In 2010, the Centers for Medicare and Medicaid Services (CMS) began covering services for patients enrolled in the Ornish program under a new category: Intensive Cardiac Rehabilitation. The criteria for eligibility is further described in the section titled Medicare National Coverage below.

In a prospective, randomized controlled trial (RCT) by Ornish et al. (1990), the investigators assigned 28 patients to an experimental group (low-fat vegetarian diet, smoking cessation, training in stress management, and moderate exercise) and 20 patients to a usual-care group in order to determine whether comprehensive lifestyle changes affect coronary atherosclerosis after 1 year.<sup>4</sup> In the analysis of 195 coronary artery lesions by quantitative coronary angiography, the average percentage diameter stenosis regressed from 40.0 (standard deviation [SD]: 16.9%) to 37.8 (SD: 16.5%) in the experimental group and progressed from 42.7 (SD: 15.5%) to 46.1 (SD: 18.5%) in the control group. In the analysis of only lesions greater than 50% stenosis, the average percentage diameter stenosis regressed from 61.1 (SD: 8.8%) to 55.8 (11.0%) in the experimental group and progressed from 61.7 (SD: 9.5%) to 64.4 (SD: 16.3%) in the control group. With an average change towards regression in 82% of the experimental-group patients, the investigators concluded that comprehensive lifestyle changes may be able to bring about regression of even severe coronary atherosclerosis after only 1 year, without the use of lipid-lowering drugs.

Ornish et al. (1998) published a RCT conducted from 1986–1992 on the feasibility of patients to sustain intensive lifestyle changes for 5 years and the effects of these changes (without lipid-lowering medications) on coronary heart disease.<sup>5</sup> Patients who had moderate to severe coronary heart disease were randomized to either the Lifestyle Modification Program (10% fat whole foods diet, aerobic exercise, stress management training, and group psychosocial support) or to a usual-care control group. The investigators found that the experimental group made and maintained comprehensive lifestyle changes for 5 years, whereas the control group had more moderate changes. The average percent diameter stenosis (assessed by quantitative coronary arteriography) at baseline decreased 1.75 absolute percentage points after 1 year (a 4.5% relative improvement) and by 3.1 absolute percentage points after 5 years (a 7.9% relative improvement) in the experimental group. In the control group, the average percent diameter stenosis increased by 2.3 percentage points after 1 year (a 5.4% relative worsening) and by 11.8 percentage points after 5 years (a 27.7% relative worsening);  $P=.001$  between groups. The control group had more than twice as many cardiac events (risk ratio for any event for the control group, 2.47 [95% confidence interval (CI): 1.48–4.20]). The investigators concluded that in the experimental group there was more regression of coronary atherosclerosis occurring after 5 years than after 1 year. In the control group, coronary atherosclerosis continued to progress and more than twice as many cardiac events occurred.

Gould et al. (1992) conducted a randomized, controlled, blinded arteriographic trial to determine the effects of the Lifestyle Modification Program on geometric dimensions, shape, and fluid dynamic characteristics of coronary artery stenosis.<sup>6</sup> All stenosis dimensions were analyzed, including proximal, minimal, distal diameter, integrated length, exit angles and exit effects, determining stenosis shape and a single integrated measure of stenosis severity, stenosis flow reserve reflecting functional severity. Complex shape change and a stenosis-molding characteristic of statistically significant progressing severity occurred with worsening of stenosis flow reserve in the control group. In the treated group, complex shape change and stenosis molding characteristic of significant regressing severity was observed with improved stenosis flow reserve in the treatment group. The results of the study documented the multidimensional characteristics of regressing coronary artery disease.

In a RCT by Gould et al. (1995) the investigators sought to quantify changes in size and severity of myocardial perfusion abnormalities by positron emission tomography (PET) in patients with coronary artery disease after 5 years of risk factor modification.<sup>7</sup> Patients were randomized to the Lifestyle Modification Program or to usual care by their physician, consisting primarily of antianginal therapy. Results of the study showed that size and severity of perfusion abnormalities on dipyridamole PET images decreased (improved) after risk factor modification in the experimental group whereas the

control group had an increase (worsening) of size and severity. The percentage of left ventricle perfusion abnormalities outside 2.5 SDs of those of normal persons (based on 20 disease-free individuals) on the dipyridamole PET image of normalized counts worsened in controls (mean  $\pm$  SE,  $+10.3\% \pm 5.6\%$ ) and improved in the experimental group (mean  $\pm$  SE,  $-5.1\% \pm 4.8\%$ ;  $P=.02$ ). The percentage of left ventricle with activity less than 60% of the maximum activity on the dipyridamole PET image of normalized counts worsened in controls ( $+13.5\% \pm 3.8\%$ ) and improved in the experimental group ( $-4.2\% \pm 3.8\%$ ;  $P=.002$ ). The myocardial quadrant on the PET image with the lowest average activity expressed as a percentage of maximum activity worsened in controls ( $-8.8\% \pm 2.3\%$ ) and improved in the experimental group ( $+4.9\% \pm 3.3\%$ ;  $P=.001$ ). The size and severity of perfusion abnormalities on resting PET images were significantly improved in the experimental group in comparison to the control group. The relative magnitude of changes in size and severity of PET perfusion abnormalities was comparable to or greater than the magnitude of changes in percent diameter stenosis, absolute stenosis lumen area, or stenosis flow reserve documented by quantitative coronary arteriography. The authors concluded that modest regression of coronary artery stenoses after risk factor modification is associated with decreased size and severity of perfusion abnormalities on rest-dipyridamole PET images.

In a RCT by Pischke et al. (2008) the authors looked at psychological well-being during the Lifestyle Heart Trial.<sup>8</sup> Psychological distress, anger, hostility, and perceived social support were compared by group (intervention,  $n=28$ ; control,  $n=20$ ) and time (baseline, 1 year, and 5 years) and examined the relationships of lifestyle changes to cardiac variables. Reductions in psychological distress and hostility in the experimental group (when compared with controls) were observed after 1 year;  $p<0.5$ . By 5 years, improvements in diet were related to weight reduction and decreases in percent diameter stenosis. Improvements in stress management were related to decreases in percent diameter stenosis at both follow-ups; all  $p<0.5$ . The findings of this study show the importance of targeting multiple health behaviors in secondary prevention of coronary heart disease.

Pischke et al. (2007) looked at whether changes in lifestyle are feasible and beneficial in patients with coronary heart disease who have a left ventricular ejection fraction (LVEF)  $<40\%$ .<sup>9</sup> A group of 50 patients with angiographically documented LVEF  $\leq 40\%$  (mean:  $33.4 \pm 7.3$ ; range: 15–40%) was compared to 186 patients with LVEF  $>40\%$  (mean:  $58.2 \pm 9.6$ ; range: 42–87%). All were participants in the Multicenter Lifestyle Demonstration Project (MLDP) and were non-smokers. Coronary risk factors, lifestyle and quality of life (SF-36) were assessed at baseline, 3 and 12 months. The authors found that patients showed significant improvements (all  $p<0.05$ ) in lifestyle behaviors, body weight, body fat, blood pressure, resting heart rate, total and LDL-cholesterol, exercise capacity, and quality of life by 3 months, regardless of LVEF. Most improvements were maintained over 12 months.

In a study by Frattaroli et al. (2008), the authors investigated the effects of intensive lifestyle modification on symptom relief.<sup>10</sup> Changes in angina pectoris, coronary risk factors, quality of life, and lifestyle behaviors were investigated in patients with stable coronary artery disease who were enrolled in the multisite cardiac lifestyle intervention program (an ongoing health insurance-covered lifestyle intervention conducted at 22 sites in the United States). Non-smoking patients with coronary artery disease were asked to make changes in diet, engage in moderate exercise, and practice stress management (757 men, 395 women; mean age 61 years). At baseline, 108 patients (43% women) reported mild angina while 174 patients (37% women) reported limiting angina. After 12 weeks, 74% of the patients were angina free, and an additional 9% who reported limiting angina at baseline, now reported mild angina. This improvement in angina was significant for patients with mild and limiting angina at baseline regardless of gender;  $p<0.01$ . Significant improvements in cardiac risk factors, quality of life, and lifestyle behaviors were observed. Those patients with angina who became angina free by 12 weeks showed the greatest improvements in exercise capacity, depression, and health-related quality of life;  $p<0.05$ . The authors concluded that by making intensive lifestyle changes, patients could drastically reduce their need for revascularization procedures.

Silberman et al. (2010) investigated the effectiveness of an ICR program in improving health outcomes at multiple sites.<sup>11</sup> The study included 2,974 men and women from 24 socio-economically diverse sites who participated in an ICR program. Changes in cardiovascular disease were assessed at baseline, 12 weeks, and 1 year. Results of the study showed that 88% of patients remained enrolled in the program after 12 weeks and 78.1% remained enrolled in the program after 1 year. Statistically significant improvements were seen after 12 weeks in BMI, triglycerides, LDL, total cholesterol, HbA1c, systolic blood pressure, diastolic blood pressure, depression, hostility, exercise, and functional capacity. These differences also remained significant after 1 year. The authors concluded that the intensive cardiac rehabilitation program was feasible and sustainable for most patients and was associated with the numerous subjective and objective improvements in health outcomes.

In a study by Daubenmier et al. (2007), the authors evaluated the additive and interactive effects of 3-month changes in health behaviors (dietary fat intake, exercise, and stress management) on 3-month changes in coronary risk and psychosocial factors among 869 non-smoking CHD patients (24% female) enrolled in the Multisite Cardiac Lifestyle Intervention Program.<sup>12</sup> Health behaviors, coronary risk factors, and psychosocial factors were analyzed at baseline and 2-months. Multiple regression analysis evaluated changes in dietary fat intake and hours per week of exercise and stress management as predictors of changes in coronary risk and psychosocial factors. Results showed the following:

- A significant overall improvement in coronary risk
- Reductions in dietary fat intake predicted reductions in weight, total cholesterol, low-density lipoprotein cholesterol, and interacted with increased exercise to predict reduction in perceived stress
- Increase in exercise predicted improvements in total cholesterol and exercise capacity (for women)
- Increased stress management was related to reductions in weight, total cholesterol/high-density lipoprotein cholesterol (for men), triglycerides, hemoglobin A1c (in patients with diabetes), and hostility

The authors concluded that improvements in dietary fat intake, exercise, and stress management were individually, additively, and interactively related to coronary risk and psychosocial factors. The results suggest that multicomponent programs focusing on diet, exercise, and stress management may benefit patients with coronary heart disease.

Koertge et al. (2003) published a study examining the medical and psychosocial characteristics of 440 patients (mean age 58 years, 21% women) with coronary artery disease at baseline and at 3-month and 12-month follow-ups.<sup>13</sup> All patients were participants in the Multicenter Lifestyle Demonstration Project. Significant improvements in diet, exercise, stress management practices, medical factors (e.g., plasma lipids, blood pressure, body weight, exercise capacity) and psychosocial factors (e.g., quality of life) were maintained by both genders over the course of the study. The authors concluded that these results demonstrate a multi-component lifestyle change program focusing on diet, exercise, stress management, and social support can be successfully implemented at hospitals in diverse regions of the United States.

In 2011, Chainani-Wu et al. conducted a prospective cohort study of 131 patients (59.2% women and 43.1% with diabetes mellitus), 56 with coronary heart disease (37.5% women and 27.3% diabetes mellitus), and 75 at high risk with  $\geq 3$  coronary heart disease risk factors and/or diabetes mellitus (76% women and 54.7% diabetes mellitus).<sup>14</sup> The purpose of the study was to evaluate the changes in emerging cardiac biomarkers, cognitive function, and social support measures after a comprehensive lifestyle intervention which included a low-fat, whole-foods, plant-based diet, exercise, stress management, and group support meetings. Improvement in all targeted health behaviors was seen in both high-risk and CHD groups (all  $p < 0.001$ ) at 3 months, with reductions in body mass index, systolic and diastolic blood pressure, waist/hip ratio, C-reactive protein, insulin, low-density lipoprotein, high-density and total cholesterol, apolipoproteins A1 and B (all  $p < 0.009$ ) were observed.

The quality of life, cognitive functioning, and social support measures significantly improved. The authors concluded that lifestyle changes can be followed by favorable changes in traditional and emerging coronary heart disease biomarkers, quality of life, social support, and cognitive function among those with, or at high risk, of coronary heart disease.

### Summary of Evidence

By following an intensive cardiac rehabilitation program such as the Ornish Program for Reversing Heart Disease; many studies have shown benefits in patients with heart disease and those at risk of heart disease. The evidence has shown improved quality of life (stress reduction, physical function, and overall well-being), risk factor improvements, and fewer cardiac events. For patients with any of the conditions described in the policy statement above, intensive cardiac rehabilitation programs (i.e., Dr. Dean Ornish Program for Reversing Heart Disease) may be considered medically necessary.

### Supplemental Information

#### Practice Guidelines and Position Statements

#### American College of Cardiology/American Heart Association

The AHA/ACC 2013 guideline on lifestyle management to reduce cardiovascular risk recommends specific dietary and physical activity needs for lowering LDL and blood pressure.<sup>15</sup> The recommendations for both LDL and blood pressure are as follows:

#### Diet

Consume a dietary pattern that emphasizes intake of vegetables, fruits, and whole grains; includes low-fat dairy products, poultry, fish, legumes, nontropical vegetable oils, and nuts; and limits intake of sweets, sugar-sweetened beverages, and red meats.

- a. Adapt this dietary pattern to appropriate calorie requirements, personal and cultural food preferences, and nutrition therapy for other medical conditions (including diabetes).
- b. Achieve this pattern by following plans such as the DASH dietary pattern, the USDA Food Pattern, or the AHA Diet.

#### Physical Activity

##### *Lipids*

1. In general, advise adults to engage in aerobic physical activity to reduce LDL-C and non-HDL-C: 3–4 sessions per wk, lasting on average 40 min per session, and involving moderate- to vigorous-intensity physical activity.

##### *Blood Pressure*

1. In general, advise adults to engage in aerobic physical activity to lower BP: 3–4 sessions per wk, lasting on average 40 min per session, and involving moderate- to vigorous-intensity physical activity.

#### Medicare National Coverage

There is a National Coverage Determination (NCD) for Ornish Program for Reversing Heart Disease (20.31.2).<sup>16,1</sup>

##### *Cardiac Rehabilitation/ICR Program Beneficiary Coverage*

- Effective January 1, 2010, Medicare Part B covers Cardiac Rehabilitation and ICR program services for beneficiaries who have experienced one or more of the following:
  - An acute myocardial infarction within the preceding 12 months;
  - A coronary artery bypass surgery;
  - Current stable angina pectoris;
  - Heart valve repair or replacement;
  - Percutaneous transluminal coronary angioplasty or coronary stenting;

- A heart or heart-lung transplant; or
- Other cardiac conditions as specified through a national coverage determination (NCD) (Cardiac Rehabilitation only).

#### *Cardiac Rehabilitation/ICR Program Component Requirements*

- Covered Cardiac Rehabilitation and ICR programs must include the following components:
  - *Physician-prescribed exercise* - This physical activity includes aerobic exercise combined with other types of exercise (i.e., strengthening, stretching) as determined to be appropriate for individual patients by a physician each day Cardiac Rehabilitation /ICR items/services are furnished.
  - *Cardiac risk factor modification* - This includes education, counseling, and behavioral intervention, tailored to the patients' individual needs.
  - *Psychosocial assessment* - This assessment means an evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation. It should include an assessment of those aspects of the individual's family and home situation that affects the individual's rehabilitation treatment and a psychosocial evaluation of the individual's response to (and rate of progress under) the treatment plan.
  - *Outcomes assessment* - These should include: (1) minimally, assessments from the commencement and conclusion of Cardiac Rehabilitation /ICR, based on patient-centered outcomes which must be measured by the physician immediately at the beginning and end of the program, and (2) objective clinical measures of the effectiveness of the Cardiac Rehabilitation /ICR program for the individual patient, including exercise performance and self-reported measures of exertion and behavior.
  - *An individualized treatment plan* - This plan should be written and tailored to each individual patient and include (1) a description of the individual's diagnosis,(2) the type, amount, frequency, and duration of the Cardiac Rehabilitation /ICR items/services furnished, and (3) the goals set for the individual under the plan. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

#### *Cardiac Rehabilitation Sessions Frequency Limitations*

- Cardiac Rehabilitation sessions are limited to a maximum of 2 one-hour sessions per day (up to 36 sessions, over a period of up to 36 weeks), with the option for an additional 36 sessions over an extended period of time if approved by the Medicare contractor under Section 1862(a)(1)(A) of the Social Security Act.
- ICR sessions are limited to 72 one-hour sessions, up to 6 sessions per day, over a period of up to 18 weeks.

## References

1. Centers for Medicare and Medicaid Services (CMS). Provider Inquiry Assistance: Cardiac Rehabilitation and Intensive Cardiac Rehabilitation – JA6850. 2010. Accessed April 07, 2021 from <http://www.cms.gov/Medicare/Medicare-Contracting/ContractorLearningResources/downloads/JA6850.pdf>
2. Centers for Disease Control and Prevention (CDC). Heart Disease Facts. Page last reviewed October 14, 2022. Accessed April 14, 2023 from <http://www.cdc.gov/heartdisease/facts.htm>
3. Preventive Medicine Research Institute. Ornish Spectrum – Reversing Heart Disease Program. Accessed April 14, 2023 from <https://www.ornish.com/undo-it/>
4. Ornish D, Brown SE, Scherwitz LW et al. Can Lifestyle Changes Reverse Coronary Heart Disease: The Lifestyle Heart Trial. Lancet. 1990; 336:129-33.



- Documentation for Clinical Review

- History and physical and/or consultation notes including:
  - Documented cardiac history
  - Smoking history and cessation date
- Prior cardiac procedure report(s)

## Coding

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for*



clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	None	
HCPCS	G0422	Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session
	G0423	Intensive cardiac rehabilitation; with or without continuous ECG monitoring; without exercise, per session
	S9472	Cardiac rehabilitation program, nonphysician provider, per diem

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
11/26/2014	Custom Policy
04/08/2015	Coding update
04/01/2016	Policy revision without position change
04/01/2017	Policy revision without position change
04/01/2018	Policy revision without position change
03/01/2019	Policy revision without position change
05/01/2020	Annual review. No change to policy statement. Literature review updated.
05/01/2021	Annual review. No change to policy statement. Policy guidelines and literature updated.
06/01/2022	Annual review. No change to policy statement. Policy guidelines and literature updated.
05/01/2023	Annual review. Policy statement, guidelines and literature updated.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

## Appendix A

POLICY STATEMENT	
BEFORE <u>Red font: Verbiage removed</u>	AFTER <u>Blue font: Verbiage Changes/Additions</u>
<p>Lifestyle Modification Program for Reversing Heart Disease BSC8.01</p> <p><b>Policy Statement:</b> Intensive cardiac rehabilitation (ICR, i.e., Dr. Dean Ornish Program for Reversing Heart Disease) may be considered <b>medically necessary</b> in <b>patients</b> when <b>both</b> of the following are met:</p> <ol style="list-style-type: none"> <li>I. Non-smoker or have quit smoking at least 3 months prior to enrolling in program</li> <li>II. Have experienced <b>one or more</b> of the following conditions: <ol style="list-style-type: none"> <li>A. Acute myocardial infarction (MI) within the preceding 12 months</li> <li>B. Coronary artery bypass surgery</li> <li>C. Current stable angina pectoris</li> <li>D. Heart or heart-lung transplant</li> <li>E. Heart valve repair or replacement</li> <li>F. Percutaneous transluminal coronary angioplasty or coronary stenting</li> </ol> </li> </ol>	<p>Lifestyle Modification Program for Reversing Heart Disease BSC8.01</p> <p><b>Policy Statement:</b></p> <ol style="list-style-type: none"> <li>I. Intensive cardiac rehabilitation (ICR, i.e., Dr. Dean Ornish Program for Reversing Heart Disease) may be considered <b>medically necessary</b> in <b>individuals</b> when <b>both</b> of the following are met: <ol style="list-style-type: none"> <li>A. Non-smoker or have quit smoking at least 3 months prior to enrolling in program</li> <li>B. Have experienced <b>one or more</b> of the following conditions: <ol style="list-style-type: none"> <li>1. Acute myocardial infarction (MI) within the preceding 12 months</li> <li>2. Coronary artery bypass surgery</li> <li>3. Current stable angina pectoris</li> <li>4. Heart or heart-lung transplant</li> <li>5. Heart valve repair or replacement</li> <li>6. Percutaneous transluminal coronary angioplasty or coronary stenting</li> </ol> </li> </ol> </li> </ol>