CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 125	Date: September 24, 2010
	Change Request 7113

SUBJECT: Intensive Cardiac Rehabilitation (ICR) Programs - Dr. Ornish's Program for Reversing Heart Disease and the Pritikin Program

I. SUMMARY OF CHANGES: Effective for claims with dates of service August 12, 2010, and after, CMS has determined that the Ornish Program for Reversing Heart Disease and the Pritikin Program each meet the ICR program requirements set forth by Congress in section 1861(eee)(4)(A) of the Social Security Act and in regulations at 42 CFR 410.49(c) and, as such, both programs have been included on the list of approved ICR programs available at http://www.cms.gov/MedicareApprovedFacilitie/.

This revision [to the Medicare National Coverage Determinations Manual] is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries,[contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions], quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: AUGUST 12, 2010
IMPLEMENTATION DATE: October 25, 2010

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
N	1/20.31/Intensive Cardiac Rehabilitation (ICR) Programs
N	1/20.31.1/Pritikin Program (Effective August 12, 2010)
N	1/20.31.2/Ornish Program for Reversing Heart Disease (Effective August 12, 2010)

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Unless otherwise specified, the effective date is the date of service.

Attachment - Business Requirements

Pub. 100-03	Transmittal: 125	Date: September 24, 2010	Change Request: 7113

SUBJECT: Intensive Cardiac Rehabilitation (ICR) Programs - Dr. Ornish's Program for Reversing Heart Disease, and the Pritikin Program

EFFECTIVE DATE: AUGUST 12, 2010
IMPLEMENTATION DATE: October 25, 2010

I. GENERAL INFORMATION

A. Background: 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. It must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in 5 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. To implement these coverage provisions, the Centers for Medicare & Medicaid Services (CMS) added 42 CFR §410.49 through rule making in the CY 2010 Physician Fee Schedule Final Rule effective January 1, 2010. See 74 FR 62004 - 62005 (November 25, 2009). Also see CR 6850, TR 1974, TR 170, TR 126, and TR 339, dated May 21, 2010, and CR 6938, TR 347, dated July 15, 2010.

Individual ICR programs must be approved through the national coverage determination (NCD) process to ensure that they demonstrate these accomplishments. CMS internally generated the analyses of the Ornish and Pritikin programs to determine if they meet the statutory and regulatory requirements for approval as ICR programs under the Medicare program.

The Ornish Program for Reversing Heart Disease (also known as the Multisite Cardiac Lifestyle Intervention Program, the Multicenter Cardiac Lifestyle Intervention Program, and the Lifestyle Heart Trial Program) was initially described in the 1970s and 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 Pritikin diet was designed and adopted by Nathan Pritikin in 1955. The diet was modeled after the diet of the Tarahumara Indians in Mexico, which consisted of 10% fat, 13% protein, 75-80% carbohydrates, and provided 15-20 grams per day of crude fiber with only 75 mg/day of cholesterol. Over the years, 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.

B. Policy: Effective for claims with dates of service on and after August 12, 2010, CMS has determined that the Ornish Program for Reversing Heart Disease and the Pritikin Program each meet the ICR program requirements set forth by Congress in §1861(eee)(4)(A) of the Act and in regulations at 42 CFR §410.49(c) and,

as such, both programs have been included on the list of approved ICR programs available at http://www.cms.gov/MedicareApprovedFacilitie/.

NOTE: Contractors should refer to Pub. 100-02, Transmittal 126, CR 6850, dated May 21, 2010, Pub. 100-04, Transmittal 1974, CR 6850, dated May 21, 2010, Pub. 100-06, Transmittal 170, CR 6850, dated May 21, 2010, Pub. 100-08, Transmittal 339, CR 6850, dated May 21, 2010, noted above for detailed claims processing, coverage, coding, and payment information regarding ICR. No additional claims processing instructions are required to implement this CR.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7113.1	Contractors shall be aware that effective for claims with dates of service on and after August 12, 2010, two ICR Programs, namely, the Ornish Program for Reversing Heart Disease, and the Pritikin Program, are Medicare-approved ICR programs and will be covered under Part B. See Pub. 100-03, NCD Manual, chapter 1, section 20.31.1 and 20.31.2, Pub. 100-02, Benefit Policy Manual, chapter 15, section 232, Pub. 100-04, Claims Processing Manual, chapter 32, section 140, and chapter 26, section 10.8.3, Pub. 100-06, chapter 6, section 420, and Pub. 100-08, chapter 15, section 4.2.8, for further details.	X		X	X						
7113.2	Contractors shall not mass-adjust claims from August 12, 2010, until the implementation date of this CR. However, contractors may adjust claims that are brought to their attention.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7113.3	A provider education article related to this instruction will be available at	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.										

IV. SUPPORTING INFORMATION

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

V. CONTACTS

Pre-Implementation Contact(s): Sarah McClain, Coverage, 410-786-2994, sarah.mcclain@cms.hhs.gov, Pat Brocato-Simons, Coverage, 410-786-0261, patricia.brocatosimons@cms.hhs.gov, Wanda Belle, Coverage, 410-786-1851, wanda.belle@cms.hhs.gov, Bill Ruiz, Institutional Claims Processing, 410-786-9283, william.ruiz@cms.hhs.gov, Tom Dorsey, Practitioner Claims Processing, thomas.dorsey@cms.hhs.gov, 410-786-7434.

Post-Implementation Contact(s): Appropriate regional office

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: ***For Medicare Administrative Contractors (MACs)*****:**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

Medicare National Coverage Determinations Manual
Chapter 1, Part 1

Table of Contents
(Rev.125,Issued: 09-24-10)

20.31 – Intensive Cardiac Rehabilitation (ICR) Programs
(Rev.125, Issued: 09-24-10, Effective: 08-12-10, Implementation: 10-25-10)

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.

20.31.1 - The Pritikin Program (Effective August 12, 2010)
(Rev. 125, Issued: 09-24-10, Effective: 08-12-10, Implementation: 10-25-10)

A. General

The Pritikin diet was designed and adopted by Nathan Pritikin in 1955. The diet was modeled after the diet of the Tarahumara Indians in Mexico, which consisted of 10% fat, 13% protein, 75-80% carbohydrates and provided 15-20 grams per day of crude fiber with only 75 mg/day of cholesterol. Over the years, 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.

B. Nationally Covered Indications

Effective for claims with dates of service on and after August 12, 2010, the Pritikin Program meets the intensive cardiac rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act and in regulations at 42 C.F.R. §410.49(c) and, as such, has been included on the list of approved ICR programs available at http://www.cms.gov/MedicareApprovedFacilitie/.

C. Nationally Non-Covered Indications

Effective August 12, 2010, if a specific ICR program is not included on the list as a Medicare-approved ICR program, it is non-covered.

D. Other

N/A
(This NCD last reviewed August 2010.)

20.31.2 – Ornish Program for Reversing Heart Disease (Effective August 12, 2010)
(Rev.)

A. General

The Ornish Program for Reversing Heart Disease (also known as the Multisite Cardiac Lifestyle Intervention Program, the Multicenter Cardiac Lifestyle Intervention Program, and the Lifestyle Heart Trial Program) was initially described in the 1970s and 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.

B. Nationally Covered Indications

Effective for claims with dates of service on and after August 12, 2010, the Ornish Program for Reversing Heart Disease meets the Intensive Cardiac Rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act, and in regulations at 42 C.F.R. §410.49(c) and, as such, has been included on the list of approved ICR programs available at http://www.cms.gov/MedicareApprovedFacilitie/.

C. Nationally Non-Covered Indications

Effective August 12, 2010, if a specific ICR program is not included on the list as a Medicare-approved ICR program, it is non-covered.

D. Other

N/A

(This NCD last reviewed August 2010.)