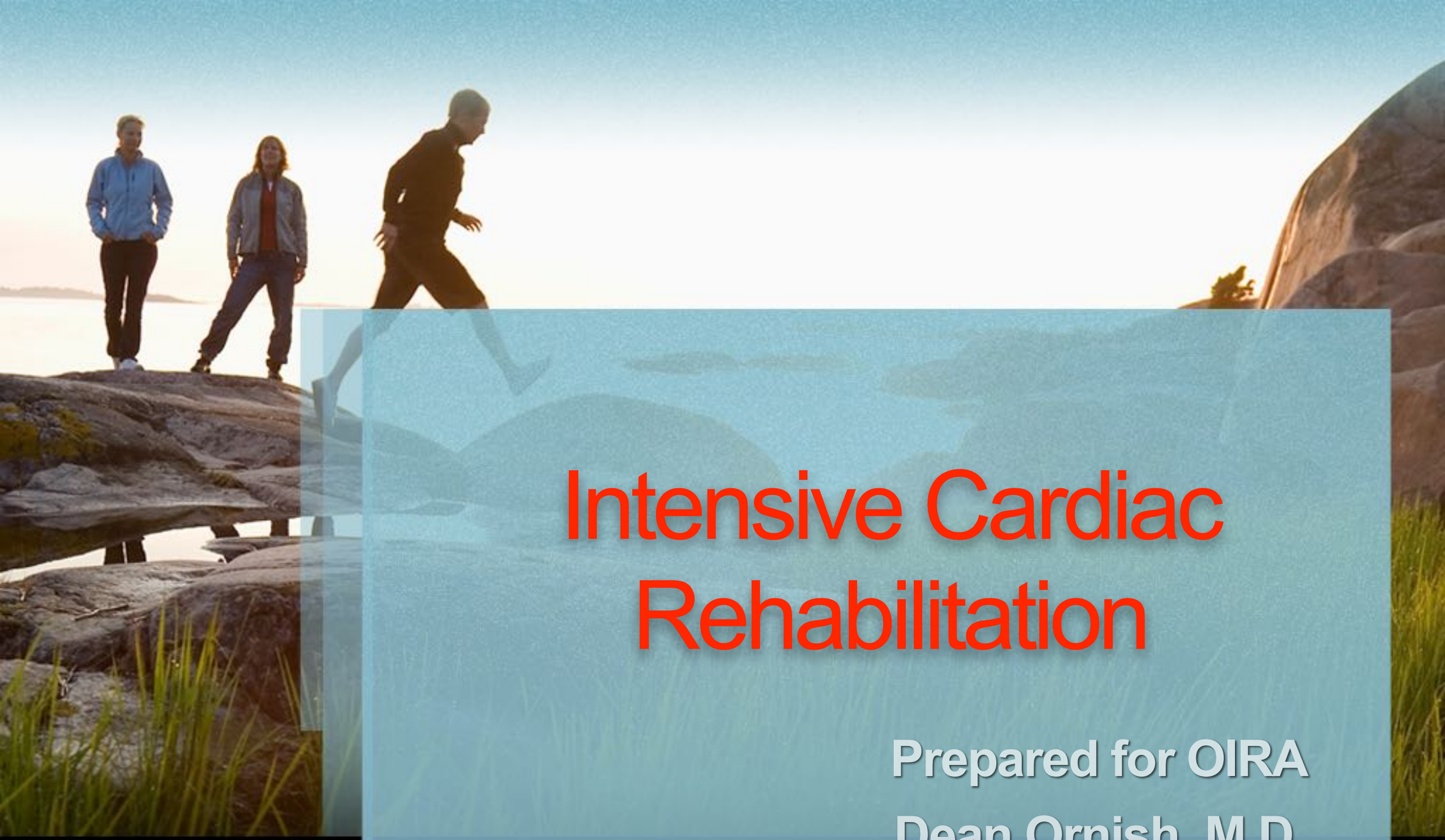


Intensive Cardiac Rehabilitation

Prepared for OIRA

Dean Ornish, M.D.

Founder & President
Preventive Medicine Research Institute
Clinical Professor of Medicine
University of California, San Francisco

Optimal Lifestyle Program

- Whole foods diet naturally low in fat & refined carbohydrates
- Stress management
- Moderate exercise
- Support groups

The "Ornish diet" has been rated "#1 for Heart Health" by a panel of experts at *U.S. News & World Report* for ten years from 2011-2021

Best Heart-Healthy Diets

Being overweight is just one factor that puts people at risk for heart disease and stroke. A heart-healthy diet can help you lose weight or lower cholesterol, blood pressure or triglycerides. According to experts who rated the 35 diets below, the Ornish Diet is the most heart-healthy.

Ornish Diet

★★★★½ (4.6 out of 5.0)

Ornish Diet recipes | Ornish Diet reviews

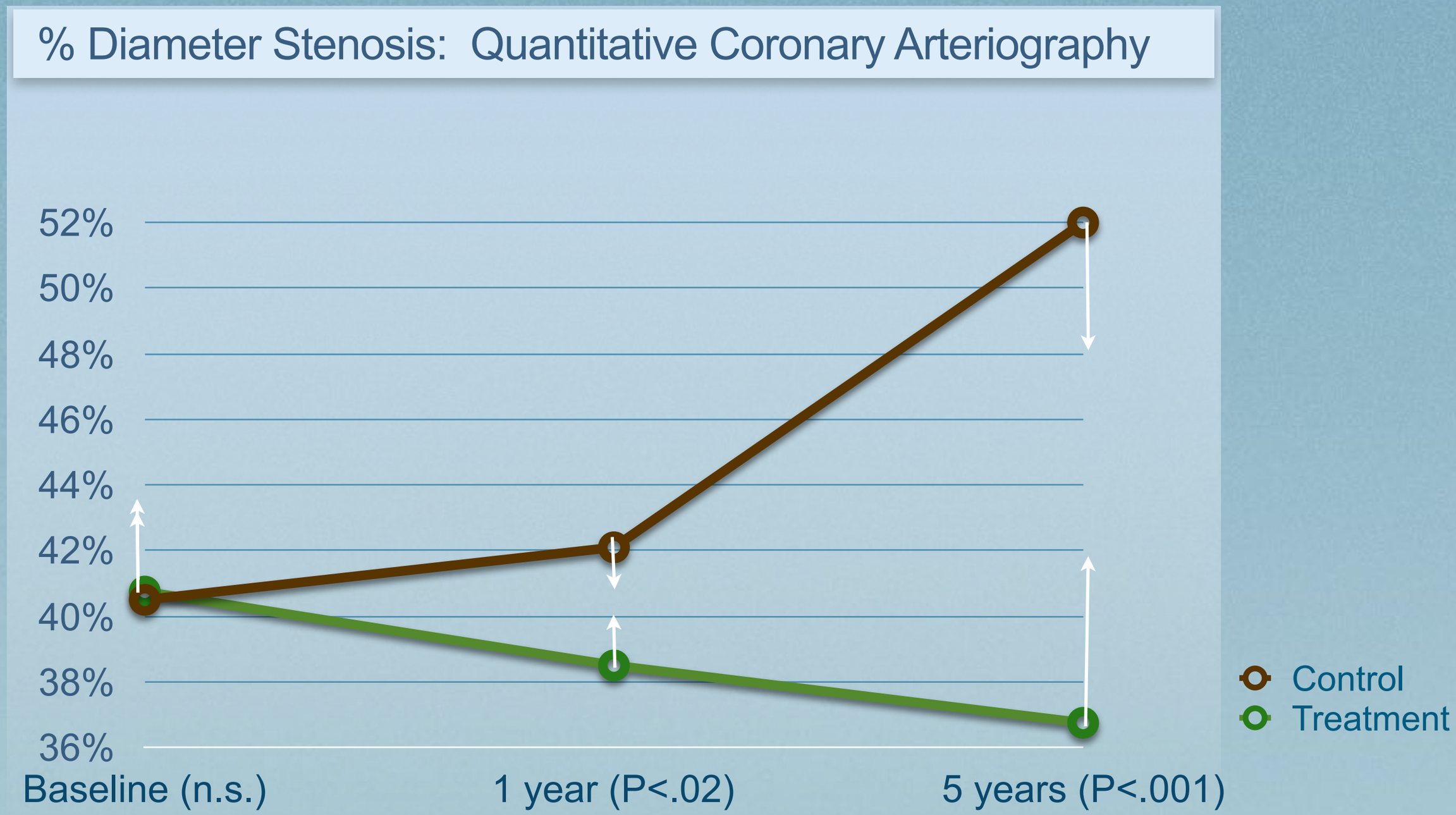
Dieters are sure to do their heart a favor on the Ornish diet, according to experts, and if they use a rigorous version of the plan they could actually reverse heart disease. But the balanced, sound menu promotes heart health only *if* – experts emphasized if – the diet's rules are followed.

How the Ornish Diet works

Overview

- This is the only program scientifically proven to reverse coronary heart disease in randomized trials and demonstration projects published in leading peer-reviewed medical and scientific journals over 44 years with lifestyle changes alone, without drugs or surgery.
- Studies have documented bigger changes in lifestyle, better clinical outcomes, larger cost savings, and better adherence in over 15,000 patients who have gone through this ICR program.

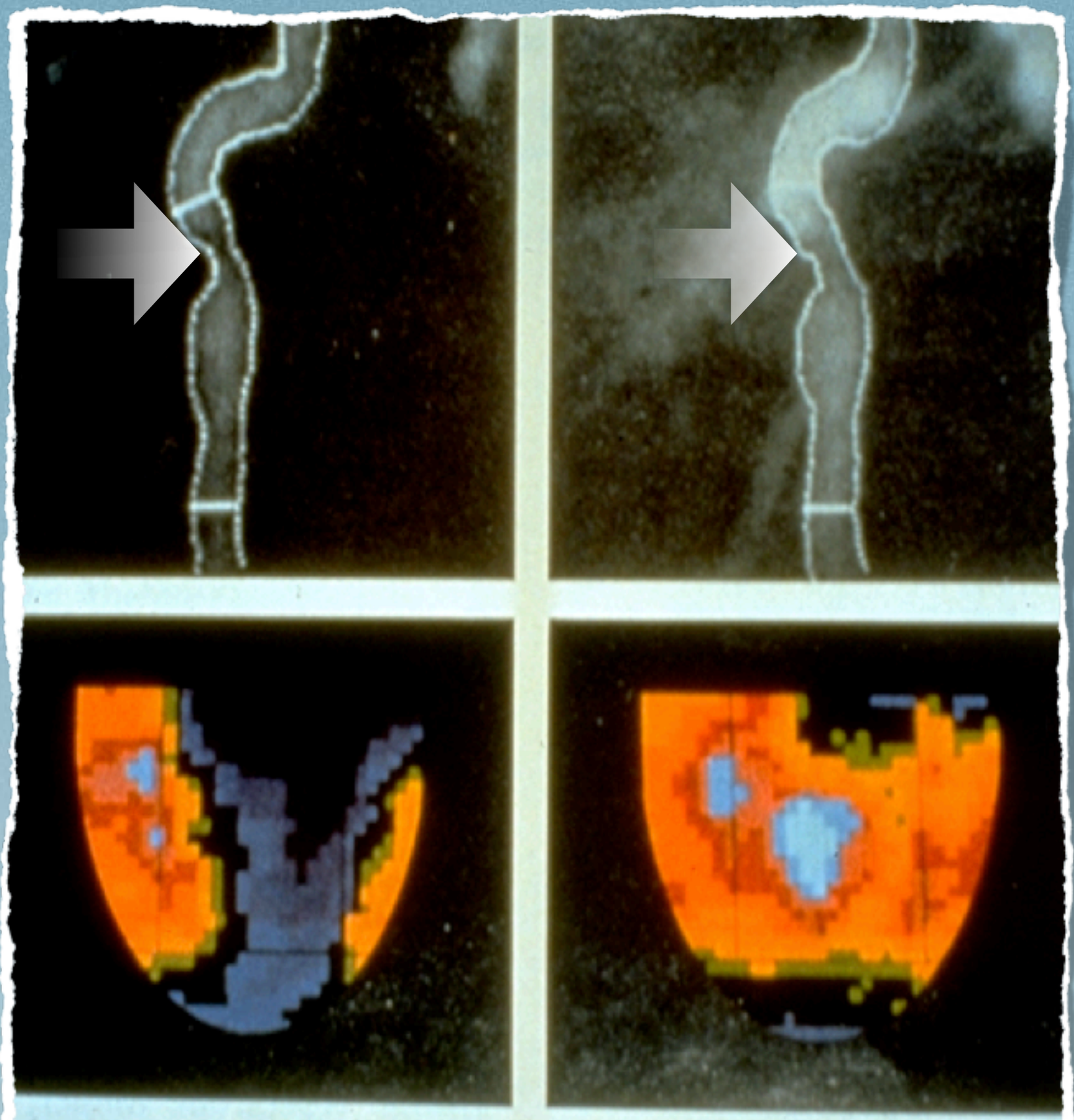
Lifestyle Heart Trial



Ornish D et al. Lancet. 1990; 336:129 & JAMA. 1998;280:2001.

There was a 400% improvement in coronary blood measured by cardiac PET scans after 5 years.

--Gould KL, Ornish D, et al. *JAMA*. 1995;274:894-901.



ure 2. Quantitative coronary angiograms and cardiac PET scans obtained

99% of patients stopped or reversed their heart disease as measured by cardiac PET scans after 5 years.

In contrast, 45% of controls got worse, 50% showed no change, and only 5% improved (p = 0.03).

--Gould KL, Ornish D, et al. *JAMA*. 1995;274:894-901.


SAN FRANCISCO, CA

Overview

- In 2010, CMS created a new benefit category, “Intensive Cardiac Rehabilitation,” or ICR.

CMS.gov
Centers for Medicare & Medicaid Services

<< Back to National Coverage Analyses (NCA) Details for Intensive Cardiac Rehabilitation (ICR) Program - Dr. Ornish's Program for Reversing Heart Disease

Decision Memo for Intensive Cardiac Rehabilitation (ICR) Program - Dr. Ornish's Program for Reversing Heart Disease (CAG-00419N)

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Decision Summary

The Centers for Medicare and Medicaid Services (CMS) has determined that 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 our 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/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/.

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Decision Memo

To: Administrative File CAG-00419N

From: Louis B. Jacques, MD
Director, Coverage and Analysis Group

Tamara Syrek Jensen, JD
Deputy Director, Coverage and Analysis Group

Marcel E. Salive, MD, MPH
Director, Division of Medical and Surgical Services

Sarah McClain, MHS
Lead Analyst, Division of Medical and Surgical Services

Joseph Chin, MD, MS
Lead Medical Officer, Division of Medical and Surgical Service

Patients come for four-hour sessions, twice/week, for nine weeks (72 hours):

- 1 hour of supervised exercise
- 1 hour of stress management
- 1 hour of group support
- 1 hour group meal + lecture

94% of patients complete all 72 hours, and 85-90% are still adhering to it one year later.

1 The Multicenter Lifestyle Demonstration Project

- Almost 80% of 333 patients who were eligible for bypass surgery or angioplasty were able to safely avoid it by choosing this ICR program as a direct alternative.

Ornish D. Avoiding revascularization with lifestyle changes: The Multicenter Lifestyle Demonstration Project. American Journal of Cardiology. 1998; 82: 72T–76T.

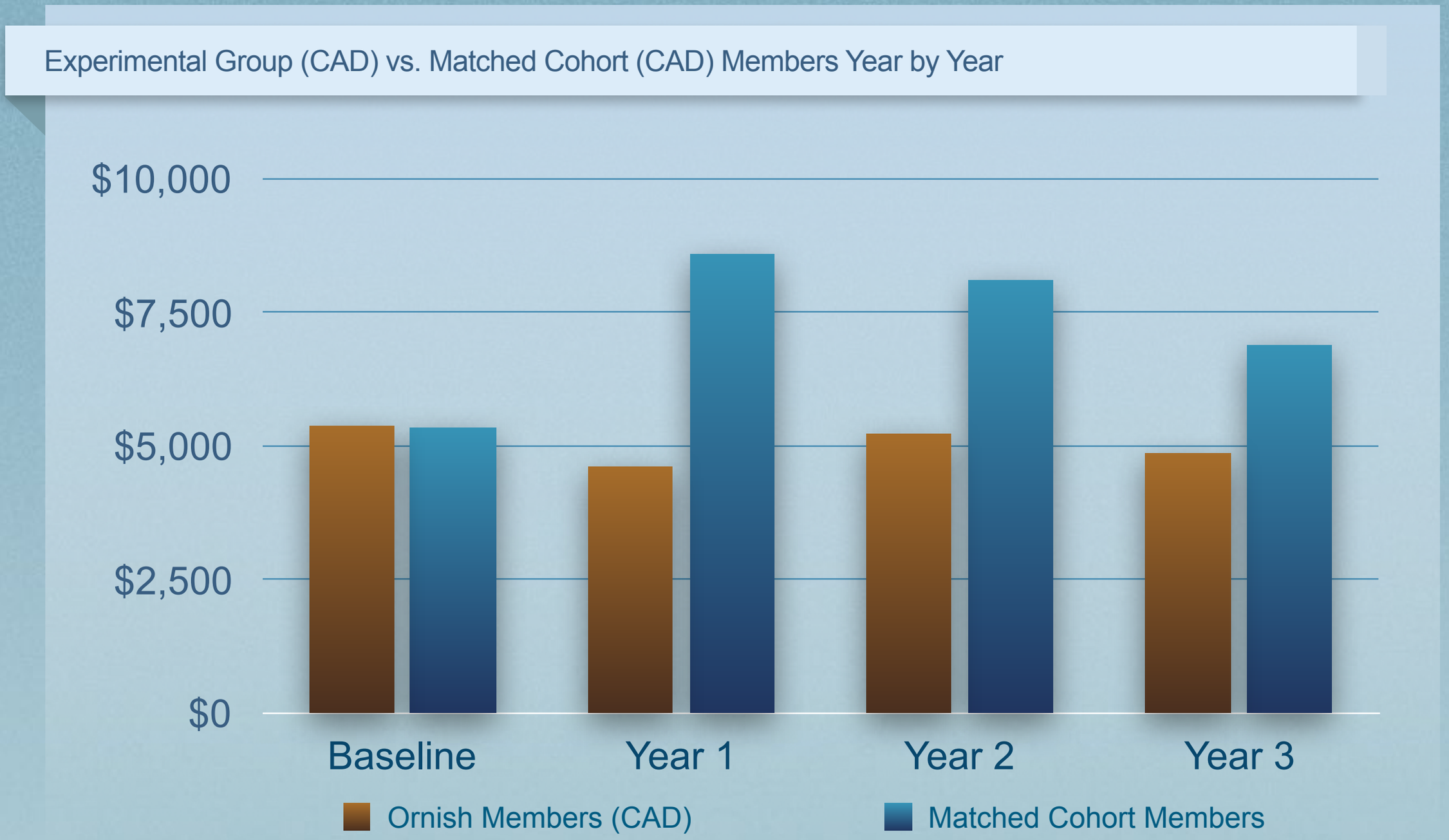
Koertge J, Weidner G, Elliott-Eller M, et al. Improvement in medical risk factors and quality of life in women and men with coronary artery disease in the Multicenter Lifestyle Demonstration Project. American Journal of Cardiology. 2003; 91: 1316–1322.

Mutual of Omaha calculated saving almost $30,000 per patient in the first year.

Ornish D. Avoiding revascularization with lifestyle changes: The Multicenter Lifestyle Demonstration Project. American Journal of Cardiology. 1998; 82: 72T–76T.

Koertge J, Weidner G, Elliott-Eller M, et al. Improvement in medical risk factors and quality of life in women and men with coronary artery disease in the Multicenter Lifestyle Demonstration Project. American Journal of Cardiology. 2003; 91: 1316–1322.

2 The Highmark Blue Cross Blue Shield Demonstration Project: Cost Comparisons After 3 Years



Experimental Group (CAD) (N=75) Baseline vs. 3 year average=8.7% decrease in costs
Matched Cohort Members (CAD) (N=75) Baseline vs. 3 year average= 47.2% increase in costs

Highmark BCBS High Cost Study

In the year after entering our lifestyle program, there was a 400% reduction in patients with claims costs greater than $25,000 compared to matched controls.

Overview

The agency posed 4 questions to stakeholders on this issue:

- Whether and to what extent hospitals have relied upon this flexibility (i.e., virtual presence) during the PHE;

- Whether providers expect this flexibility would be beneficial outside of the PHE;

- Whether we should continue to allow direct supervision for these services to include presence of the supervising practitioner via two-way, audio/video communication technology permanently, or for some period of time after the conclusion of the PHE or beyond December 31, 2021, to facilitate a gradual sunset of the policy;

- Whether there are safety and/or quality of care concerns regarding adopting this policy beyond the PHE and what policies CMS could adopt to address those concerns if the policy were extended post-PHE.

Overview

- Whether and to what extent hospitals have relied upon this flexibility (i.e., virtual presence) during the PHE:

  ICR was virtualized in March 2020 due to the COVID-19 pandemic, as it was no longer safe to meet with coronary heart disease patients (a vulnerable population) in a closed room with others who were perspiring and breathing rapidly while exercising. Because of this, ICR programs offered at hospitals shut down.

  CMS began providing coverage for ICR when offered virtually since October 2020 during the PHE.

  Without this flexibility, ICR programs would not be available to Medicare beneficiaries. Virtual coverage has been essential.

Overview

- Whether providers expect this flexibility would be beneficial outside of the PHE:

  Continuing to provide ICR programs when offered virtually will make this scientifically proven program available to heart patients living throughout the U.S., whether or not they live near a hospital, including those in rural areas.

  Also it will reduce health inequities in vulnerable populations, including minorities and lower socioeconomic groups.

  Some experts believe that we will not reach herd immunity for a long time.

The New York Times

May 3, 2021, updated May 11, 2021

Reaching 'Herd Immunity' Is Unlikely in the U.S., Experts Now Believe

Widely circulating coronavirus variants and persistent hesitancy about vaccines will keep the goal out of reach. The virus is here to stay, but vaccinating the most vulnerable may be enough to restore normalcy.

"There is widespread consensus among scientists and public health experts that the herd immunity threshold is not attainable — at least not in the foreseeable future, and perhaps not ever.

"Instead, they are coming to the conclusion that rather than making a long-promised exit, the virus will most likely become a manageable threat that will continue to circulate in the United States for years to come, still causing hospitalizations and deaths but in much smaller numbers."

Overview

- Whether we should continue to allow direct supervision for these services to include presence of the supervising practitioner via two-way, audio/video communication technology permanently, or for some period of time after the conclusion of the PHE or beyond December 31, 2021, to facilitate a gradual sunset of the policy:

The supervising physician can offer direct supervision via two-way audio/video communication. In our ICR program, the patient's own personal physician provides this supervision and is immediately available via mobile phone. Since the patient's own physician knows the patient well, they are best qualified to provide this supervision which would not be possible in a hospital setting.

We have a similar request via the PFS to add ICR to Category 3, which would continue coverage of ICR when offered virtually until the end of CY 2023. This will provide CMS with valuable additional information on safety, efficacy, and costs which can then be used to make an informed decision on whether to make this virtual coverage permanent. This is to everyone's advantage.

Overview

- Whether there are safety and/or quality of care concerns regarding adopting this policy beyond the PHE and what policies CMS could adopt to address those concerns if the policy were extended post-PHE:

My comment to CMS provides a detailed review of peer-reviewed clinical studies documenting that cardiac rehabilitation when done at home by patients with heart disease using two-way audio/video technology is as safe as when done in a hospital setting.

Now, given COVID-19, it is likely even safer since putting patients in a closed room while exercising adds another level of risk that can be avoided when done at home.