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Louis Jacques, MD
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid services
7500 Security Blvd, Mail Stop S3-02-01
Baltimore, MD 21244

RE: Formal Request for an NCD for ICR Certification

Dear Dr. Jacques:

We are writing to formally request the Center for Medicare and Medicaid Services (CMS) consider designation of the Benson-Henry Institute's (BHI) Cardiac Wellness Program (CWP) as an Intensive Cardiac Rehabilitation Program (ICR). We are quite proud of the 2009 CMS sponsored **Evaluation of Lifestyle Modification Program Demonstration**, which showed the effectiveness of our program, and which set in motion the establishment of ICR coding at CMS.

Our understanding is that in order for CMS to cover ICR, a program must:

1. Demonstrate through peer-reviewed, published research that it has accomplished one or more of the following:

- A) Positively effected progression of coronary heart disease (CHD).
- B) Reduced the need for coronary bypass surgery.
- C) Reduced the need for percutaneous coronary interventions.

We believe we meet this criterion with the publication of a recent peer-reviewed paper that assessed 3-year hospitalization rates, Medicare costs, and mortality for our program (called MBMI in the paper) as well as the Dr. Dean Ornish Program for Reversing Heart Disease Program (which has already obtained CMS ICR approval), to be published in the May issue of the American Heart Journal:

Zeng WU, Stason, WB, Fournier, S, Razavi, M, Ritter, G, Strickler, GK, Bhalotra, SM, Shepard, DS.. Benefits and costs of intensive lifestyle modification programs for symptomatic coronary disease in Medicare beneficiaries. (Am Heart J. 2013; 0: 1-8.) (In press).

In this paper we demonstrated that our CWP has a positive effect on the progression of CHD and reduces the need for coronary interventions. This impression is supported by the favorable changes in cardiac risk factors and cardiac function that were achieved. Systolic blood pressure, total serum cholesterol, and cardiac function all improved during the intense period of the intervention, and improvements were maintained or improved further at 12 and 24 months in participants with active follow-up. Significant reductions in total cardiac hospitalizations were found. in the BHI, MBMI CWP and there was even a trend toward decreased mortality at 3 years in comparison to matched control subjects in the CMS database who had treatment as usual or traditional cardiac rehabilitation.

2. Demonstrate through peer-reviewed, published research 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:

- A) Low density lipoprotein
- B) Triglycerides
- C) Body mass index
- D) Systolic blood pressure
- E) Diastolic blood pressure
- F) The need for cholesterol, blood pressure, and diabetes medications

We believe we meet this criterion with the following publication:

Casey A, Chang BH, Huddleston J, Virani N, Benson H, Dusek JA. A model for integrating a mind/body approach to cardiac rehabilitation: outcomes and correlators. J Cardiopulm Rehabil Prev. 2009 Jul-Aug; 29 (4):230-8.

In this paper, men and women demonstrated statistically, significant improvements in medical outcomes (blood pressure, lipids, weight, exercise conditioning, frequency of symptoms of chest pain and shortness of breath) and psychological outcomes (general severity index, depression, anxiety, and hostility) ($P < .0001$). Patients considered "at higher risk" for cardiac events due to high baseline measures improved their measures to a less than "at higher risk" level. Data indicate that specific components of the intervention, that is, increased relaxation response practice and exercise, significantly contributed to these improvements ($P < .05$).

The papers referred to above are attached for your review.

Please feel free to contact me at 617/726/5758 or email gfricchione@partners.org if you have any additional questions.

Thank you for your consideration of our request.

Sincerely yours,



Gregory Fricchione, MD
Director, Benson-Henry Institute for Mind Body Medicine
Massachusetts General Hospital



Herbert Benson, MD
Director Emeritus, Benson-Henry Institute for Mind Body Medicine
Massachusetts General Hospital



Aggie Casey, RN, MS
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