Medicare May Cover Diet, Lifestyle Programs

BY JOYCE FRIEDEN
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BALTIMORE — There might not have been thunderous applause at last month's meeting of the Medicare Coverage Advisory Committee, but the quiet approval was quite enough for Dean Ornish, M.D.

The committee, which advises Medicare on coverage issues, voted to recommend that Medicare cover the use of physician-supervised intensive diet and lifestyle change programs for preventing and reversing heart disease—programs such as the one developed by Dr. Ornish.

"I'm pleased by the opportunity to have all the evidence considered," he said after the panel approved the recommendation, adding that he hoped that the evidence was compelling enough for Medicare to make this type of lifestyle intervention a part of its benefits package.

Medicare is not obligated to accept the recommendation of its advisory committee.

Dr. Ornish, president of the Preventive Medicine Research Institute, Sausalito, Calif., outlined his program, which consists of putting patients on a very low-fat diet (about 10% fat), getting them on a moderate exercise program, teaching them stress management techniques such as stretching and meditation, and enrolling them in support groups.

In a 1-year study of 28 patients who took part in the program and 20 controls, he found that the average percentage diameter stenosis regressed from 40% to 37.8% in the experimental group, compared with an average progression from 42.7% to 46.1% in the control group.

In addition, there was a 91% reduction in angina in the intervention group, compared with a 165% increase in the control group.

Dr. Ornish also investigated whether other providers could be trained to implement his program, so he set up demonstration projects in other sites with more than 2,000 patients.

In the first project, funded by Mutual of Omaha, the researchers studied 194 patients with angiographically documented coronary artery disease and compared them with 139 controls. Although no patients in the intervention group had had a recent cardiac event, 55% had had a prior myocardial infarction, compared with 28% of controls.

The researchers found that after 3 years, 77% of intervention patients who met insurance company criteria to undergo bypass or angioplasty were able to avoid it, saving Mutual of Omaha $30,000 per patient, Dr. Ornish reported.

He admitted that his program requires a lot of commitment. For the first few months, participants attend two 4-hour sessions, each consisting of exercise, meditation or other stress reduction, a support group meeting, and a lunch/lecture. Later, they decrease to once-weekly sessions, but continue for 9 months.

In a payment demonstration project for Medicare, Dr. Ornish found that patients' body weight decreased both at 12 weeks and at 1 year.

He noted that the primary determinant of how much patients improved on the program was adherence. "The more people changed, the better they got," he said.

Advisory committee members expressed several concerns about Dr. Ornish's results.

Clifford Goodman, Ph.D., a senior scientist with the Lewin Group, a Falls Church, Va., consulting firm, noted that some of the improvements in the patient groups started to reverse slightly after a year, and speculated that many patients may be self-selecting for the program at a time when their weight and other negative indicators are at their peak. "How much of the effect we're observing is simply regression to the mean?" he asked.

Dr. Ornish admitted that there was some regression but added, "there is a direct correlation between degree of adherence and outcomes at 1 year."

Adherence was a concern for several panel members who wondered whether patients could really keep up with strict regimens such as Dr. Ornish's.

But Dr. Ornish said he was merely asking for these types of programs to be treated the same way as other interventions.

VIVIAN E. LEE

Many insurers pay for statins even though patients go off the drugs after a few months, Dr. Dean Ornish noted at the meeting.

"We will pay for bypass surgery and angioplasty, but diet and lifestyle interventions, Medicare generally doesn't pay for it," he said, adding that many insurers pay for cholesterol-lowering statin drugs even though studies have shown that patients go off the drugs after a few months because they don't like the side effects.

Also testifying were spokesmen from two Blue Cross Blue Shield plans—Mountain State in West Virginia and Highmark in Pennsylvania—that pay patients to enroll in the Ornish program. Both said their plans were happy with the clinical outcomes and the cost savings.

David Lambert, vice president of health services for Mountain State Blue Cross Blue Shield, said his plan began covering the Ornish program for heart disease prevention in 2002.

More than 400 patients, average age 56, have participated, with a 90% completion rate, Mr. Lambert said. "They collectively reduced their risk of a cardiac event by 50% as measured by the ATP Framingham risk tool, and lowered their LDL by 21%."

He noted that the average cost of the behavioral management program was $5,700, compared with the average cost of heart surgery, which ranges from $57,000 to $67,000. "By avoiding one procedure, it pays for 10 members to complete the program."

The committee also heard from Alex Clark, Ph.D., of the University of Alberta's Centre for Health Evidence in Edmonton. The Centers for Medicare and Medicaid Services contracted with Dr. Clark's center to review outcomes studies for patients with symptomatic coronary artery disease undergoing one of three types of therapy: cardiac rehabilitation (group education and counseling only), comprehensive cardiac rehabilitation (such as Dr. Ornish's program, which includes exercise in addition to group education and counseling), and individual counseling. All studies had to have outcomes for at least 50 patients to be included in the review.

The reviewers found that all three types of programs had some long-term benefits, including reductions in mortality and hospitalization, and improved quality of life, Dr. Clark said. "The foundation for change is happening at 12 months."

Information on program costs was sketchier, he noted. Only 6 out of 41 studies mentioned costs, and three of those "reported or implied" cost savings without giving any relevant data. Most of the studies were heavy on male participants, with seven studies having no women at all.

In the end, panel members generally agreed that the Ornish program and similar interventions improved patients' long-term survival rates and quality of life, but they were less certain that other providers would be able to successfully implement the program and that it could be easily translated to Medicare patients, many of whom have multiple chronic illnesses. ■

Benefit of Heart Failure Disease Management Scrutinized

BY BRUCE JANCIN
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NEW ORLEANS — Participation in a disease management program for heart failure resulted in a moderate survival benefit but no objective improvement in functional capacity, no reduction in health care utilization, and no cost savings in the largest and most rigorous study to date of any disease management program.

The lack of demonstrable cost savings is a key finding. Disease management is a trendy public policy issue now, with Medicare and many state Medicaid programs actively pushing disease management programs for depression, diabetes, and other chronic diseases as a means of saving money, Autumn Dawn Galbreath, M.D., observed at the annual scientific sessions of the American Heart Association.

"There's a great deal of money being spent on disease management at this time in anticipation of promised cost savings. According to our study, those promises may be empty," said Dr. Galbreath, vice chairman for clinical programs in the department of medicine at the University of Texas, San Antonio.

Prior studies which concluded that disease management programs are both clinically effective and cost-effective were small, nonrandomized, and/or based upon relatively homogeneous HMO populations.

Recognition of these deficiencies provided the impetus for the South Texas Congestive Heart Failure Disease Management Project, in which 1,069 patients with systolic or diastolic heart failure were randomized 2:1 to a disease management program or usual care and followed for 18 months, she explained.

Subjects in the disease management group were assigned a nurse case manager who provided in-depth patient education and recommended medication changes in accord with national heart failure guidelines to the patient's primary care physician, although whether or not to follow the recommendations was left to the physician's discretion.

Patients randomized to disease management survived an average of 76 days longer than controls over the course of 18 months of follow-up. However, their performance on a standard 6-minute walking test wasn't significantly better than that of controls, and neither was their mean left ventricular ejection fraction. The disease management program did not reduce hospitalizations, office or ER visits, procedures, or medications.

Subgroup analysis suggested the survival benefit was greatest in patients with New York Heart Association class III and IV systolic heart failure. But even in these patients with more severe heart failure, disease management did not result in economic savings.

"If you factor in the cost of having to pay for the disease management services, disease management actually costs money over and above the cost of traditional care," Dr. Galbreath said. The investigators plan to analyze the data further to obtain cost-benefit ratios. ■