CMS Backs Coverage for Diet, Lifestyle Changes

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BALTIMORE — There might not have been thunderous applause at the 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. "Just on weight loss alone, I think a program like this could be beneficial." He said that the primary determinant of how much patients improved on the program was adherence. "The more people changed, the better they got," he noted.

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 that of Dr. Ornish.

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

"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 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.

"This is a spectacular example of personalized health care," said William F. Owen Jr., M.D., a professor of medicine at Duke University, Durham, N.C. "I believe this works in a certain patient segment that's cared for by very passionate providers, but I'm uncomfortable about extrapolating it."

Now that the advisory committee has made its recommendation, CMS must decide whether to take up the issue of a national coverage determination, and what scope that potential coverage might have. An agency spokesman said there is no timetable for making the decision. ■

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