Panel Backs Coverage for Diet, Lifestyle Change

BY JOYCE FRIEDEN
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BALTIMORE — Physician-supervised intensive diet and lifestyle change programs for secondary prevention of cardiovascular disease have gained the endorsement of the Medicare Coverage Advisory Committee.

The committee voted to recommend that Medicare cover such programs in patients with documented cardiovascular disease, including the program developed by Dean Ornish, M.D. "I'm pleased by the opportunity to have all the evidence considered," he said.

Medicare is not obliged to accept the recommendation of the 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.

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.

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

VIVIAN E. LEE

Dr. Dean Ornish said Medicare should cover lifestyle interventions the same way as other heart disease treatments.

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. "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, he 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 said, noting 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.

A CMS spokesman said there is no timetable for when a national coverage determination will be made. ■

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MedPAC Recommends Keeping Specialty Hospitals on Hold

BY JENNIFER SILVERMAN
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WASHINGTON — Congress should extend the Medicare Modernization Act's moratorium on the construction of physician-owned specialty hospitals for another 18 months, a federal advisory panel has recommended.

The Medicare Payment Advisory Commission in draft recommendations had set the extension for 1 year, but later changed it to 18 months after commission members decided that more time was needed to study the full impact of these hospitals.

MedPAC data indicate that specialty hospitals tend to concentrate on certain diagnosis-related groups (DRGs), treating relatively lower-severity patients, and lower shares of Medicaid patients. So far, they've had little financial impact on community hospitals, MedPAC analysts claim.

Commissioners at a January meeting decided to forgo tougher language that would have eliminated the "whole hospital" exemption, a provision in the self-referral regulations that allows physicians to refer patients to a hospital in which they have an investment interest as long as the interest is in the entire hospital.

Eliminating the exemption "is not the right step to take at this time due to the limited amount of data … on specialty hospitals and their performance," MedPAC chairman Glenn Hackbarth said.

Existing specialty hospitals and hospitals under development were still eligible for the whole hospital exemption under the 2003 Medicare reform law, but new hospitals were not, effectively placing a moratorium on their construction.

The original moratorium, set to expire in June, would be effective until Jan. 1, 2007, if MedPAC's recommendation were adopted.

In a statement, Rick Pollack, executive vice president of the American Hospital Association, commended MedPAC for extending the moratorium. "This decision sends an important message to Congress that physician ownership and self-referral can cause serious conflict of interest concerns," he said.

In other recommendations slated for MedPAC's March report to Congress, commissioners voted on several measures to refine the DRGs used to determine hospital payments to better account for differences in severity of illness among patients:

▶ The Department of Health and Human Services should base the DRG relative weights on the estimated cost of providing care rather than on charges, and on the national average of hospitals' relative values in each DRG.

▶ Congress should give the Department of Health and Human Services authority to adjust the DRG relative weights to account for differences in the prevalence of high-cost outlier cases. In addition, case-mix measurement and outlier policies should be developed over a transitional period.

▶ HHS should have authority to regulate gainsharing arrangements between physicians and hospitals to protect quality of care and minimize financial incentives that could affect referrals. ■