CMS Clarifies Bariatric Surgery Coverage Criteria

BY JOYCE FRIEDEN

Senior Editor

Medicare will not cover bariatric surgery for beneficiaries who have type 2 diabetes but do not have a body mass index greater than 35 kg/m², according to a proposed decision memo.

Recent medical reports have claimed that bariatric surgery may be helpful for such patients, but the Centers for Medicare and Medicaid Services "did not find convincing medical evidence that bariatric surgery improved health outcomes for non–morbidly obese individuals," it said in a statement.

Dr. Barry Straube, the agency's director of its Office of Clinical Standards and Quality, said, "Limiting coverage of bariatric surgery in type 2 diabetic patients whose BMI is less than 35 is part of Medicare's ongoing commitment to ensure access to the most effective treatment alternatives with good evidence of benefit, while limiting coverage where the current evidence suggests the risks outweigh the benefits."

The proposal also clarifies that type 2 diabetes is one of the comorbidities that would be acceptable criteria for surgery.

In 2006, the CMS issued a national coverage decision for bariatric surgery in morbid obesity. It said Medicare would cover three procedures—open and laparoscopic Roux-en-Y gastric bypass surgery, open and laparoscopic biliopancreatic diversion with duodenal switch, and laparoscopic adjustable gastric banding—for beneficiaries with a BMI greater than 35, at least one comorbidity related to obesity, and who had been previously unsuccessful with medical treatment for obesity.

At that time, the agency asked for comments on whether Medicare should cover various gastric and intestinal bypass procedures to improve diabetes status in obese, overweight, and nonoverweight diabetes patients.

The proposed decision memo is an outcome of that query; the CMS accepted comments on the memo until mid-December. The agency had up to 30 days to issue a final decision memo, which is available online at www.cms.hhs.gov/mcd/index_list.asp?list_type=nca; click on "Surgery for Diabetes.")

Dr. Jeffrey Mechanick, who cochaired a bariatric surgery guidelines committee for the American Association of Clinical Endocrinologists, said that the CMS was responding to a trend in the medical literature and meeting presentations suggesting that bariatric surgery might be helpful for even those diabetes patients who are not overweight. "A lot of surgeons began noticing that after bariatric surgery, patients with diabetes had amelioration of their hyperglycemia. … But they found that a lot of the improvement was independent of weight loss; there was something else," he said.

There were two hypotheses: proximal changes, such as factors in the proximal small bowel, and distal changes, such as glucagonlike protein-1 and other factors made by the small bowel in the distal ileum, said Dr. Mechanick, who is also director of metabolic support in the division of endocrinology, diabetes, and bone disease at the Mount Sinai School of Medicine, in New York.

He noted that although the CMS does not currently cover the surgery for patients with a BMI under 35 that could change if long-term follow-up data on the procedure became available.

Dr. Schauer said he was pleased that the agency reaffirmed its support for surgery for diabetes patients with the standard BMI threshold of 35 kg/m² or above. "Of all insurers private and public, CMS has had the most expansive coverage of surgery so far; a lot of private carriers either don't cover the surgery at all or put a lot of non–evidence-based hurdles in front of access to care," he noted. ■

Medicare Advisers Back CT Colonography, With Caveats

BY ALICIA AULT

Associate Editor, Practice Trends

BALTIMORE — After a daylong discussion, a panel of Medicare advisers tentatively said they support use of computed tomographic colonography to screen for colorectal cancer in average-risk Medicare beneficiaries.

The Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) was given an overview of existing evidence on sensitivity, specificity, and cost-effectiveness of the technology, and then was asked to vote on a series of questions gauging panelists' level of confidence in computed tomographic colonography (CTC) as a screening tool, when compared with optical colonoscopy.

The Centers for Medicare and Medicaid Services is considering whether to offer coverage of CTC. The agency already pays for colorectal cancer screening for average-risk individuals aged 50 and older using fecal occult blood testing, sigmoidoscopy, colonoscopy, and barium enema. In March, the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology issued new cancer screening guidelines, which included the statement that CTC was an acceptable option.

A majority of the MEDCAC panelists were moderately to highly confident that there is sufficient evidence to determine sensitivity and specificity of CTC in screening for polyps that measure 6 mm to less than 10 mm, and for polyps larger than 10 mm. They were less confident that the evidence could determine specificity and sensitivity for polyps smaller than 6 mm.

Most panelists said that CTC would provide a net health benefit for average-risk Medicare beneficiaries—that is, a decrease in morbidity and mortality from identification and removal of polyps, when balanced against the risks of the procedure and the identification of extracolonic abnormalities.

But many committee members said they were quite concerned about those extracolonic findings, and said that they could skew both the health benefits of the procedure and its potential cost-effectiveness.

Dr. Mary Barton, scientific director of the U.S. Preventive Services Task Force, told the panel that the task force's systematic review of CTC found that it was comparable to optical colonoscopy in sensitivity and specificity for lesions larger than 10 mm, but not quite similar for lesions larger than 6 mm.

Colonoscopy has the potential for serious harm in 28 per 10,000 patients, partly because of the risk of perforation, Dr. Barton said. While CTC has no significant harms per 18,000 patients, there is uncertainty regarding the radiation exposure, extracolonic findings, and false positives, she said.

Dr. Ned Calonge, chairman of Preventive Services Task Force and chief medical officer of the Colorado Department of Public Health and Environment, said that the unknowns about these potential harms led the group to give CTC a grade of "I," for insufficient evidence. "This is really a call for further research," Dr. Calonge told the Medicare advisers.

Dr. Jason Dominitz of the University of Washington, Seattle, who spoke on behalf of the American Society for Gastrointestinal Endoscopy, agreed that the jury was still out on CTC. "It's our overall belief that it's premature to endorse CTC for average-risk Medicare beneficiaries at this time," Dr. Dominitz told the committee.

The screening should be offered to people with incomplete colonoscopies or to those who refuse to undergo that test, but otherwise, there are too many questions, including questions about its sensitivity for small and flat polyps, how to manage extracolonic findings, the radiation risk, and the appropriate intervals for CTC screening, he said. ■

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