POLICY & PRACTICE

Special Medicare Advantage Criteria

Medicare officials have identified 15 chronic conditions that would make individuals eligible for enrollment in a Chronic Care Medicare Advantage Special Needs Plan. The conditions were selected by a panel of advisors as being medically complex, substantially disabling or life threatening, and as having a high risk of hospitalization or adverse outcome. Included are certain neurologic disorders, stroke, chronic alcohol and other drug dependence, certain autoimmune disorders, cancer excluding precancer conditions, certain cardiovascular disorders, chronic heart failure, dementia, diabetes, end-stage liver disease, end-stage renal disease requiring dialysis, certain severe hematologic disorders, HIV/AIDS, certain chronic lung disorders, and certain chronic and disabling mental health conditions. The list of conditions is part of new guidelines for the special needs plans that will go into effect in 2010. Medicare officials noted the list is an effort to ensure that the plans stay focused on a specific population and do not expand to the larger Medicare Advantage population.

HHS Releases Quality Measures

The Department of Health and Human Services has released its first-ever inventory of the quality measures its agencies use for reporting, payment, and quality improvement. The HHS measure inventory is available from the National Quality Measures Clearinghouse, a Web site run by the Agency for Healthcare Research and Quality, and is designed to advance collaboration within the quality measurement community and to synchronize measurement, according to the HHS. "This effort is pivotal to achieving the goal of transparency in quality measurement as a cornerstone of value-driven health care," HHS Secretary Mike Leavitt said in a statement. The quality measures inventory is available online at www.qualitymeasures.ahrq.gov.

FDA Opens China Offices

The Food and Drug Administration has opened field offices in Beijing, Guangzhou, and Shanghai, China, as part of an effort to improve the safety of food and other consumer products. "A permanent FDA presence in China will help us address the challenges presented by globalization," FDA Commissioner Andrew von Eschenbach said in a statement. "We look forward to working with the Chinese government and manufacturers to ensure that FDA standards for safety and manufacturing quality are met before products ship to the United States." Establishing a permanent presence by the FDA in China will greatly enhance efforts to protect consumers in both countries and also will enable the FDA officials to help the Chinese government in its ongoing efforts to improve its regulatory systems for exports to help ensure product safety, agency officials said. The FDA also intends to open offices in other parts of the world and ultimately will have a presence in five geographic regions, including China, India, Europe, Latin America, and the Middle East, the agency said.

MedPAC Calls for Disclosure

Congress should pass legislation to require drug, device, and medical supply makers and distributors, along with hospitals, to disclose their financial ties to physicians and physician groups, the Medicare Payment Advisory Commission has decided. The companies also should be required to disclose financial relationships with pharmacies, pharmacists, health plans, pharmacy benefit managers, hospitals, medical schools, continuing medical education organizations, patient organizations, and professional organizations. The MedPAC said it will urge Congress to require drug manufacturers to post on a Web site all details about free drug samples given to providers. In addition, the MedPAC said that lawmakers should require the HHS to submit a report describing financial arrangements between hospitals and physicians. MedPAC advises Congress on Medicare issues, but lawmakers are not required to implement the commission's recommendations.

Payments Backlogged in West

Medicare payments to physicians in California, Hawaii, and Nevada have been held up because of problems stemming from the new National Provider Identifier numbers and from the transition to a new claims processor. Columbia, S.C.–based Palmetto GBA began processing fee-for-service Medicare claims for the three states in September, and the California Medical Association said that it had received calls from more than 1,000 physicians complaining of delays in payment. The transition to Palmetto has been "marred by missteps," and "the delay in payments threatens to compromise patient care and provider solvency," Rep. Henry Waxman (D-Calif.) said in a statement. To address the issue, Palmetto said in a statement that it has added 35 staffed phone lines and expects the backlog will be cleared or nearly cleared by Dec. 31.

NIMH to Study Suicides in Army

The National Institute of Mental Health has signed a memorandum of understanding with the U.S. Army to study suicide and suicidal behavior among active-duty soldiers, National Guard members, and Army Reservists. The 5-year, $50 million effort will be the largest study of suicide ever undertaken by the institute, according to an agency statement. The goal is to identify risk and protective factors for suicide and to help the Army develop effective intervention programs. In 2007, 115 Army members committed suicide; of those, 36 committed suicide while deployed, 50 did so following deployment, and 29 had never been deployed.

—Jane Anderson

CMS Clarifies Coverage For Bariatric Surgery

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/m^2, according to a proposed decision memo issued last month.

"While recent medical reports claimed that bariatric surgery may be helpful for these patients, [the Centers for Medicare and Medicaid Services] did not find convincing medical evidence that bariatric surgery improved health outcomes for non–morbidly obese individuals," according to a CMS 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."

Although the CMS is not covering the surgery for patients with a BMI under 35, that could change if long-term follow-up data become available.

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. That decision said that Medicare would cover only 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 who have a BMI greater than 35, have at least one comorbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity.

At that time, the agency then asked for comments on whether Medicare should cover various gastric and intestinal bypass procedures to improve diabetes status among 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 has up to 30 days to issue a final decision memo. (The proposed memo 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 the CMS was responding to a trend in the medical literature and meeting presentations suggesting that bariatric surgery might be helpful for diabetes patients who are not overweight.

"A lot of surgeons began noticing that after bariatric surgery, patients with diabetes had amelioration of their hyperglycemia," he said. "At first glance, it seems pretty easy—you lose weight and so your diabetes should be getting better. But they found that a lot of the improvement was independent of weight loss; there was something else."

The theories included 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, New York.

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

Dr. Philip Schauer, past president of the American Society for Metabolic and Bariatric Surgery, said he was not disappointed with the proposed decision memo. To the contrary, "we in the surgical community were somewhat surprised this came up at all because our organization was not necessarily pushing CMS to address the issue," said Dr. Schauer, who is director of the Bariatric and Metabolic Institute at the Cleveland Clinic.

"However, there is increasing evidence on bariatric surgery for patients with diabetes and BMI 30-34. When more of this evidence emerges, I think CMS will look at the issue again."

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/m^2 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.

Dr. Schauer was one of four organizers of the Diabetes Surgery Summit held in Rome in 2007 with the goal of developing consensus guidelines for gastrointestinal surgery to treat type 2 diabetes. The guidelines have been completed and were accepted for publication in the Lancet; they will probably appear early in 2009, he said. The guidelines affirm that uncontrolled type 2 diabetes patients with BMIs greater than 35 should be strongly considered for surgical intervention; they also state that for similar patients whose BMIs are less than 35 but greater than 30, surgery may be a reasonable option.

The American Diabetes Association is in agreement with the CMS proposal, a spokeswoman said. She noted that the association has stated that "people with type 2 diabetes and a BMI of 35 or above may be candidates for bariatric surgery." ■