

WILLIAM T. DENMAN, MD, FRCA
Chief Medical Officer
Vice President Medical Affairs



Dr. S. Phurrough, MD MPA
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mailstop C1-09-06
7500 Security Blvd
Baltimore, MD 21244

Re: Comment on **National Coverage Analysis for Surgery for Diabetes (CAG-00397N)**

Dear Dr. Phurrough,

We commend CMS on calling for a National Coverage Analysis on such a timely subject, Surgery for Diabetes. Covidien, formerly Tyco Healthcare, has been a long time supplier of instrumentation to the bariatric surgery community. We have agreed wholeheartedly with the previous CMS NCD for Bariatric Surgery for Treatment of Morbid Obesity (100.1) for patients with a body mass index above 35 kg/m² and having at least one co-morbidity related to obesity, especially type 2 diabetes.

Strong Clinical Evidence

We continue to believe that strong evidence supports coverage for gastric bypass, gastric banding and duodenal switch procedures in treating morbidly obese patients with diabetes^{1,2,3,4,5,6,7,8}. Indeed, data published since implementation of NCD 100.1 has shown a 92% reduction in diabetes-associated deaths in a morbidly obese patient population treated with Roux en Y gastric bypass when compared to a non-surgically treated morbidly obese population.⁹ In the landmark Swedish Obesity Study¹⁰ comparing surgical treatment to conventional treatment for morbidly obese patients, three conclusions were reached:

1. In the surgical cohort, native glycemic control was preserved when compared to the medically managed cohort (p<0.001).
2. The resolution of diabetes and recovery from metabolic syndromes was significantly greater in the surgical cohort compared to the medical cohort.
3. 24% reduction in mortality at 16 years in the surgically managed cohort versus the medically managed cohort.

We support the current CMS policy that covers beneficiaries with a BMI above 35 kg/m² and diabetes. The current NCA is an exciting prospect that will examine the further role of surgery for patients with diabetes by considering the rapidly expanding research in this area.

Several Possible Mechanisms in Surgery for Diabetes

The data regarding surgical resolution of diabetes shows that surgery may effect two mechanisms involved in the glycemic response to the prandial cycle: the entero-insular^{11,12,13,14,15,16} and adipo-insular^{17,18} axes. Observation of the neuroendocrine changes following gastric bypass surgery indicate that they may be responsible for the early improvement in diabetic obese patients prior to any substantial weight loss^{19,20,21,22} with some patients becoming euglycemic prior to discharge from the hospital after surgery^{23,24}. These mechanisms suggest that there may be other obese populations with diabetes that would benefit from a surgical intervention.

Early Clinical Data in Obese Diabetic Populations

Extension of these data suggests that there may be a role for surgical resolution of diabetes in many diabetic populations, especially those where adipose tissue reduction is warranted along with change in the neuroendocrine response. Dixon et al²⁵ have shown in randomized trials that adjustable gastric banding is more effective than medical therapy in achieving glycemic control in obese diabetic patients with diabetes (BMI > 30 or < 40 kg/m²). In this study, they showed that 73% of the surgically treated patients achieved a fasting glucose level less than 126 mg/dl and a glycosylated hemoglobin (HbA1c) level less than 6.2% compared to 13% in the conventionally treated patients.

Cohen et al²⁶ and Lee et al²⁷ have reported on the effect of gastric bypass surgery on diabetic with diabetes with a BMI less than 35kg/m². Both groups show significant weight loss after gastric bypass surgery. Cohen performed gastric bypass surgery in 37 obese patients with type 2 diabetes mellitus, hypertension, and lipid disorder. After surgery, 36 patients had remission of their comorbidities. Lee compared results of gastric bypass surgery in patients with a BMI above 35kg/m² prior to surgery to those with BMI less than 35kg/m² prior to surgery. One year after surgery, the group with an initial BMI <35 kg/m² showed that fasting plasma glucose returned to normal in 76.5% and HbA1c decreased to less than 7.0% in 92.4% of patients. Studies reporting the benefits in patients with diabetes, who are not obese, have also been reported..^{28,29}

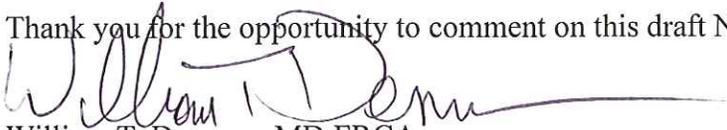
Further Clinical Research

We feel that these data show that there is a growing and important role for surgery in the treatment of diabetes. This has been clearly demonstrated in morbidly obese patients with diabetes.. The clinical and animal model research shows that there is a complex relationship between weight loss, surgery and glycemic control. It is also becoming evident that the benefits of surgery for diabetes may extend to other patient populations as well, but these patient populations need to be further defined through appropriately conducted scientific trials. We feel strongly that further evidence is needed to determine the optimal treatment algorithms for patients with diabetes, be it medical, surgical or a combination of treatment modalities. Covidien is supporting clinical (NCT00450710; NCT00456352; NCT00596973; NCT00641251; NCT00540462; NCT00534547; **Please treat these clinical research protocols as confidential and do not publicly disclose.**) as well as laboratory research to address and answer these questions.

CMS

We feel that there is overwhelming evidence to support coverage for bariatric surgery for patients with diabetes having a BMI of greater than 35 kg/m² under NCD 100.1. CMS should consider that the diagnosis of diabetes alone would warrant coverage independent of the diagnosis of obesity. Evidence also exists that there may be other populations that would benefit from a surgical intervention for diabetes and CMS should consider supporting mechanisms that would determine which populations would most benefit from a surgical intervention.

Thank you for the opportunity to comment on this draft National Coverage Analysis.



William T. Denman, MD FRCA
Chief Medical Officer and VP Medical Affairs
Medical Devices
Covidien

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