



December 16, 2008

Steve Phurrough MD, MPA
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Phurrough:

On behalf of the Obesity Action Coalition (OAC), I am writing to respond to the Centers for Medicare & Medicaid Services (CMS) request for public comment on the agency's proposed Decision Memo for Surgery for Diabetes (CAG-00397N) issued on November 17, 2008. We appreciate the Medicare program's interest in this issue.

The OAC is a national non-profit organization representing nearly 12,000 members – the majority of which have been personally affected by obesity. Our membership includes adults who are overweight, obese, morbidly obese and those who have successfully addressed their obesity, parents of children who are affected by obesity as well as concerned members of the public. In addition, our membership also includes more than one thousand healthcare providers who care for those afflicted with the disease of obesity. Our strong belief is that obesity, like other diseases, must be both prevented and treated. Those either currently obese, or at risk for developing obesity, and are ready to make a change in their lives, should have expanded access to both prevention *and* treatment avenues.

The OAC viewed CMS's February 2006 national coverage decision regarding bariatric surgery for the treatment of morbid obesity as a potential major milestone for ensuring access to surgical intervention for Medicare beneficiaries suffering from morbid obesity and the myriad of co-morbidities that accompany this disease. We applauded the agency for its thorough review of the literature regarding bariatric surgery as well as its flexibility during the public comment period to consider additional studies suggested by the medical community.

It appears that CMS has followed a similar rigorous approach to reviewing the data regarding the benefits of surgical intervention for non-morbidly obese individuals suffering from type two diabetes mellitus (T2DM). And although the OAC agrees with Medicare's decision to not lower the minimum BMI requirements regarding diabetics seeking surgery until further efficacy and safety data are available, we urge CMS to be especially vigilant as new data become available in the coming months and years.

In fact, the potential for such procedures may be so great that CMS might wish to investigate utilizing its coverage with evidence development (CED) process -- utilizing the data collection services of existing Bariatric Surgery Centers of Excellence. We agree with Medicare's CED process and that collecting additional patient data as part of the coverage process would generate more robust data on the utilization and impact of bariatric surgery on non-morbidly obese individuals suffering from T2DM. As a result, Medicare would be able to better document the appropriateness of bariatric surgery for this population and generate clinical information that will improve the evidence base on which providers base their recommendations to Medicare beneficiaries regarding bariatric surgery for diabetes.

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One major concern of the OAC revolves around how Medicare Administrative Contractors (MACs) will interpret the inclusion of T2DM as the only listed co-morbidity outlined under Section 100.1 of the Medicare Coverage Manual regarding bariatric surgery for treatment of morbid obesity. We believe that such specificity in listing T2DM could further exacerbate access to care for the morbidly obese as MACs may choose to define covered co-morbidities as only those specifically enumerated by CMS within the Coverage Manual. CMS should include all the co-morbidities that can be alleviated or eliminated post bariatric surgery such as hypertension; dyslipidemia; T2DM; coronary heart disease; stroke; gallbladder disease; osteoarthritis; sleep apnea; respiratory problems; and endometrial, breast, prostate, and colon cancers.

As we outlined to CMS coverage staff this past summer, morbidly obese patients are already facing significant roadblocks to accessing medical and surgical treatment for their disease. We fear that this recent action by CMS may further fortify, rather than breakdown, many of these obstacles. The OAC is concerned that unless specifically instructed otherwise, many MACs may interpret T2DM as the only acceptable co-morbidity and continue to apply their own additional standards limiting care (for example, requiring uncontrolled T2DM to be an acceptable candidate). We urge the agency to issue specific instructions informing MACs that the diagnosis of T2DM in any morbidly obese individual is one of many acceptable co-morbidities enumerated in the February 21, 2006 NCD, which allow for bariatric surgical treatment.

Another obstacle to care, which we discussed during the aforementioned meeting with CMS, revolves around certain MACs and their medical weight management requirements prior to bariatric surgery. While the OAC strongly believes that medical weight management should be a Medicare-covered therapy for those affected by overweight/obesity, we feel that 6-18 month mandates required by some MACs are arbitrary and intended solely as a barrier to surgical care for Medicare beneficiaries. We believe it would be more appropriate for a 3-month requirement specifically designed to educate bariatric surgery patients on the nutrition, exercise and other lifestyle changes necessary to be successful long-term.

Medical weight loss management holds promise in helping overweight and obese individuals obtain modest weight-loss. While these individuals often do not achieve "ideal" body weight, even modest weight-loss offers profound benefit in improving quality of life and preventing or delaying the onset of many of the co-morbidities previously outlined. Therefore, Medicare should provide coverage for medical weight loss management for those Medicare patients that may benefit from it as well as for those who may not, but yet are mandated by Medicare to attempt this bridge crossing in order to qualify for bariatric surgery. As is the case with coverage for treatment surrounding other diseases such as diabetes and heart disease, Medicare should provide both access to, and coverage of, a wide range of treatment options for those affected by overweight/obesity.

Thank you for the opportunity to comment. Please do not hesitate to contact me via phone at 813-872-7835 or email at jnadglowski@obesityaction.org if I can provide any additional information.

Sincerely,

A handwritten signature in black ink, appearing to read 'Joe Nadglowski, Jr.', written in a cursive style.

Joseph Nadglowski, Jr.
President and CEO
Obesity Action Coalition