American Society for Bariatric Surgery
100 SW 75th Street, Suite 201
Gainesville, FL 32607

May 11, 2005

Steve E. Phurrough, MD, MPA
Office of Clinical Standards & Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail Stop C1-09-06
Baltimore, MD 21244-1850

Re: Request for Bariatric Surgery NCD

Dear Dr. Phurrough:

The American Society for Bariatric Surgery hereby requests a National Coverage Determination (NCD) on Bariatric Surgery. Our request is being made pursuant to NCD Development Track #1 and is supported by the organizations listed below. This NCD is intended to expand the existing coverage of surgery for severe obesity under current Medicare Policy consistent with the guidelines established by the National Institutes of Health and with the recommendations of the Medicare Coverage Advisory Committee meeting held November 4, 2004. We believe this expansion, based upon sound data, will improve the health, extend the duration and enhance the quality of life of Medicare beneficiaries.

Obesity is significantly associated with five of the top ten self-reported health conditions of Medicare beneficiaries. It is associated with premature mortality and related diseases which include, but are not limited to, diabetes mellitus, most indicators of the metabolic syndrome such as hyperlipidemia and hypertension, some cancers, joint disease (hips, knees), chronic low back pain, gastro-esophageal reflux disease (GERD), pseudotumor cerebri, polycystic ovary syndrome (PCOS), sleep apnea, obesity hypoventilation, urinary incontinence, venous stasis disease, non-alcoholic liver disease ("NALD") and non-alcoholic steatohepatitis ("NASH"), chronic depression, and a decreased quality of life ("QOL"). The population eligible for bariatric surgery should include persons with a BMI $\geq$ 40 kg/m^2 regardless of co-morbidity or a BMI $\geq$ 35 kg/m^2 with obesity related co-morbidities. Adequate coverage of bariatric surgery is essential for addressing the critical health needs of the Medicare population.

As the surgical treatment for severely or morbidly obese individuals, bariatric surgery includes restrictive and malabsorptive procedures and procedures that are a combination of both approaches. Unlike non-surgical treatments, bariatric surgery has clinically demonstrated significant weight loss for individuals with a BMI of 40 or greater and a BMI of 35 or greater with comorbidities. There is substantial evidence that weight loss from bariatric surgery results in improved health outcomes as compared to non-surgical treatments. Consequently, we find that the coverage of bariatric surgery is vital to the health of morbidly obese Medicare disabled and elderly beneficiaries.

As you are aware, Medicare recently modified its rules concerning coverage of obesity. It removed language stating that obesity could not be considered an illness and revised then-existing language. As a result, Medicare today states:

> Obesity may be caused by medical conditions such as hypothyroidism, Cushing's disease, and hypothalamic lesions, or can aggravate a number

American Society for Bariatric Surgery Ê
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> of cardiac and respiratory diseases as well as diabetes and hypertension. Services in connection with the treatment of obesity are covered when such services are an integral and necessary part of a course of treatment for one of these medical conditions. However, program payment may not be made for treatment of obesity unrelated to such a medical condition since treatment in this context has not been determined to be reasonable and necessary.

National Cov. Deter. Manual (Pub. 100-3), § 40-5 (2004).

The only surgical treatment for obesity that is currently covered by a NCD is gastric bypass. This policy states "Gastric bypass surgery for extreme obesity is covered under the program if (1) it is medically appropriate for the individual to have such surgery, and (2) the surgery is to correct an illness which caused the obesity or was aggravated by the obesity". National Cov. Deter. Manual (Pub. 100-3), § 100.1 (2003). There is a strong basis for revising coverage beyond these limited situations based on the data presented to MCAC on November 4, 2004, which have been included in this request for your convenience. Additionally, a new NCD would hopefully address the inconsistent access to treatment that has been created by Local Coverage Determinations.

The MCAC Panel voted favorably on the safety and efficacy of bariatric surgery for severely obese patients and expressed confidence in all of the bariatric procedures currently used in the United States. The attached materials support this conclusion. This coverage should also extend to pre- and long-term postoperative medical, nutritional, and psychiatric assessment and care.

For these reasons, we respectfully request that the Center for Medicare and Medicaid Services (CMS) provide a National Coverage Determination (NCD) for Bariatric Surgery for morbidly obese beneficiaries which provides that:

1) Bariatric surgery is a covered service for beneficiaries with a Body Mass Index (BMI) or $\geq$ 40 kg/m^2 regardless of co-morbidity status or a BMI $\geq$ 35 kg/m^2 with one or more of the following co-morbidities:

    a) Type II diabetes mellitus
    b) Hypertension
    c) Gallbladder disease
    d) Dyslipidemia (hypertriglyceridemia, increased LDL cholesterol);
    e) Kidney disease
    f) Disorders of the reproductive system including irregular menses, frequent anovular cycles, hirsutism, and reduced fertility (polycystic ovary syndrome or Stein-Leventhal syndrome)
    g) Dermatological conditions including pressure ulcers, leg ulcers, candidiasis, furunculosis, erythrasma, folliculitis, intertrigo, lymphedema, and hidradenitis suppurativa
    h) Chronic venous insufficiency (bronze edema, venous stasis ulcer, and thrombophlebitis)
    i) Respiratory disorders including asthma, sleep apnea, and hypoventilation syndrome

American Society for Bariatric Surgery
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j) Degenerative joint disease involving the lower back, hips, knees, ankles, or feet
k) Gastroesophageal reflux
l) Urinary stress incontinence
m) Pseudotumor cerebri
n) Non-alcoholic liver disease ("NALD")
o) Non-alcoholic steatohepatitis ("NASH")
p) Chronic depression
q) Decreased quality of life ("QOL"), as measured by a 20% or more decrease in one or more domains in the RAND SF-3
r) Or any co-morbidity that a physician or surgeon determines that adversely affects a patient's normal activity of daily living.

2) The following bariatric procedures should, at a minimum, be covered:

a) open Roux-en-Y gastric bypass
b) laparoscopic Roux-en-Y gastric bypass
c) open adjustable gastric banding
d) laparoscopic adjustable gastric banding
e) open biliopancreatic diversion with duodenal switch
f) laparoscopic biliopancreatic diversion with duodenal switch
g) open vertical banded gastroplasty
h) laparoscopic vertical banded gastroplasty
i) open sleeve gastrectomy (a standard component of the biliopancreatic diversion with duodenal switch) as part of a 2-stage procedure for very high risk patients with the 2nd stage either completion of the biliopancreatic diversion with duodenal switch or Roux-en-Y gastric bypass.
j) laparoscopic sleeve gastrectomy (a standard component of the biliopancreatic diversion with duodenal switch) as part of a 2-stage procedure for very high risk patients with 2nd stage either completion of the biliopancreatic diversion with duodenal switch or Roux-en-Y gastric bypass.

In addition, local Medicare contractors should have continued discretion to cover additional procedures that may be developed which adhere to current CMS policy regarding coverage for applicable devices under Category B IDE trials (42 CFR §405.201 and the CMS routine clinical trials policy (NCD §310.1)

3) Beneficiaries would be required to have a history of a non-surgical weight loss attempt(s) that were inadequate to show an improvement in health status. Beneficiaries would not be required to engage in such non-surgical weight loss attempts in the year immediately prior to surgical intervention.

4) Pre-operative and post-operative medical, nutritional, psychological assessment and care would be stated and required.

American Society for Bariatric Surgery
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5) Providers of surgical service, including both surgeons and hospitals, would be required to participate in a national non-profit, professionally directed accrediting organization, such as the Surgical Review Corporation. The accreditation program would require long-term outcomes data submission. To support continuous quality improvement, the ASBS, in concert with the SRC, would continue to develop the components required for a national bariatric surgery patient data base. For uniformity and validity, the instruments would be based on the recently developed elements and definitions of the NIDDK Consortium for the Longitudinal Assessment of Bariatric Surgery (LABS). Future efforts would be directed to obtaining data to assist providers in determining which operation would be the most effective and appropriate for which patient. At a minimum, these centers must include the following standards:

a) An institutional commitment at the highest levels of the medical staff and the institution's administration to excellence in bariatric surgical care that is demonstrated by ongoing, regularly scheduled, in-service education programs in bariatric surgery and the adoption of credentialing guidelines for bariatric surgery.
b) An institution should be expected to perform at least 125 bariatric surgical cases each year and providers should be expected to perform at least 50 cases each year, for a period of several years.
c) A designated physician Medical Director for bariatric surgery should be available to participate in the relevant decision-making administrative meetings of the institution.
d) A full staff of the various consultative services required for the care of bariatric surgical patients should be available upon 30 minutes notice, including the immediate availability of an ACLS-qualified physician on site for patient resuscitation.
e) An institution should maintain a full line of equipment and instruments for the care of bariatric surgical patients including furniture, wheel chairs, operating room tables, beds, radiologic capabilities, surgical instruments, and other facilities suitable for morbidly obese patients.
f) An institution should have a bariatric surgeon (certified by the American Board of Surgery, or the American Osteopathic Board of Surgery, and/or Royal College of Surgeons of Australia, United Kingdom, or Canada) who spends a significant portion of his or her efforts in the field of bariatric surgery and who has qualified coverage (full care of a bariatric patient in the absence of the primary surgeon) and support for patient care.
g) A provider should utilize clinical pathways and orders that facilitate the standardization of perioperative care for the relevant procedure chosen by the provider.
h) An institution should utilize designated nurses or physician extenders who are dedicated to serving bariatric surgical patients and who are involved in continuing education in the care of bariatric patients.
i) The facility should make available organized, supervised, and documented support groups for all patients who have undergone bariatric surgery at the institution including, on-line chat rooms, web-based support groups, and exercise.
j) Providers should provide documentation of a program dedicated to a goal of

American Society for Bariatric Surgery
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long term patient follow-up of at least 75% for bariatric procedures at five years with a monitoring and tracking system for outcomes, and an agreement to make available annual outcome summaries to the reviewing entity in a manner consistent with Health Insurance Portability and Accountability Act ("HIPAA") regulations.

6) Coverage be provided for long-term postoperative follow-up care after bariatric surgery. Long-term postoperative follow-up care would be provided by health care professionals (Bariatricians, Primary Care Physicians, Internists, Surgeons) beyond the normal surgical postoperative care period. Educational programs would be developed to optimize long-term post-bariatric surgery follow-up.

Sincerely,

Harvey J. Sugerman, MD, FACS
President