



American Society for Metabolic & Bariatric Surgery

October 24, 2011
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
cc: Joseph Chin, MD, MS

Dear Dr. Berwick:

The American Society for Metabolic and Bariatric Surgery is pleased to support the recent decision by CMS to open a national coverage determination reconsideration in order to review the new evidence for the vertical sleeve gastrectomy (VSG) as a primary bariatric surgery. We are fully confident that CMS will find there is adequate evidence for evaluating health outcomes of the vertical sleeve gastrectomy for the indications listed in the current Bariatric Surgery for the Treatment of Morbid Obesity National Coverage Determination (NCD). We are aware of your particular interest in receiving evidence speaking to the health outcomes attributable to the use of VSG in the Medicare population and there is strong, supporting evidence submitted in this letter and in the attached ASMBS Vertical Sleeve Gastrectomy Position Statement. We believe it is fitting and proper that CMS support this National Care Determination for the vertical sleeve gastrectomy for the following reasons:

- 1. The Medicare population is at risk for obesity and its consequences.**
- 2. The Vertical Sleeve Gastrectomy is safe and effective and comparable to CMS covered Gastric Bypass and Gastric Banding.**
- 3. The Vertical Sleeve Gastrectomy is a unique surgical intervention appropriate for at-risk patient populations.**
- 4. The Vertical Sleeve Gastrectomy is routinely covered by other payors.**

The Medicare population is at risk for obesity and its consequences.

The Medicare population is specifically an at-risk population for obesity and its consequences. Eligibility for Medicare benefits include age >65 and disability including end-stage renal disease (ESRD). Numerous studies have detailed the impact of obesity leading to disability. In a 2008 *Obesity Review* article, Neovius and colleagues found that patients with a BMI>35 had a Three-Fold risk of being disabled. The same article highlighted the strong impact of bariatric surgery upon potential reversal of disability with a doubling of return to work for obese disabled patients who had surgical treatment

for their obesity. Flegal in a 2010 *JAMA* article found a 12.1 % incidence of BMI>35 in the population age>60. Obesity has also been found to lead to increased waiting times for ESRD patients awaiting transplant leading to weight-related disparities in care for these Medicare patients in need (Segev, *J Am Soc Nephrol*, 2008).

The Vertical Sleeve Gastrectomy is safe and effective and comparable to CMS covered Gastric Bypass and Gastric Banding.

Since the implementation of the original National Care Determination for Bariatric Surgery, we have witnessed an American surgical success story regarding patient safety in the bariatric surgery population. Encinosa detailed in a 2009 *Medical Care* article the steep decline in in-patient, 30- day and 180 day complications respectively, 37%, 24%, and 21 %. In specific to the Medicare population, Nguyen in a 2010 *Archives of Surgery* noted a 33% reduction in mortality in Medicare beneficiaries following the NCD resulting in an overall bariatric surgery mortality rate 0.2%.

There are large, multi-center prospective studies to specifically compare the perioperative outcomes of the three main bariatric surgeries. In a 2010 *JAMA* article by Birkmeyer, a Michigan state-wide collaborative for bariatric surgery demonstrated a 30 day mortality rate of 0.14% for gastric bypass, 0.04% for gastric banding and ZERO % for sleeve gastrectomy. By utilizing the NSQIP database, Hutter in a 2011 article in *Annals of Surgery* found that the vertical sleeve gastrectomy was positioned between band and bypass for both complications and weight loss.

In order to respond to receiving evidence speaking to the health outcomes attributable to the use of VSG in the Medicare population, we accessed the ASMBS Bariatric Outcomes Longitudinal Database (BOLD). BOLD is the world's largest repository of bariatric surgery outcomes and was established partly in response to the original Bariatric Surgery NCD. From 2007-2010, over 268,898 bariatric surgeries were entered and reviewed in BOLD. Below in Table 1, the safety profile of the sleeve gastrectomy is between the two CMS-sanctioned bariatric procedures of gastric bypass and band. Similarly, resource utilization as measured by Length of Stay for the sleeve gastrectomy is less than the gastric bypass but more than the gastric band.

SAFETY: GASTRIC BAND>SLEEVE GASTRECTOMY>GASTRIC BYPASS

Table 1: 30-Day Outcomes, BOLD 2007-2010

	Gastric Bypass (Roux-en-Y) N=136036	Adjustable Gastric Banding N=116898	Sleeve Gastrectomy N=15964
Deaths	186 (0.14%)	32 (0.03%)	13 (0.08%)
Serious Complications	1699 (1.25%)	298 (0.25%)	154 (0.96%)
Any Complications	15425 (11.34%)	4006 (3.43%)	1336 (8.37%)

	Gastric Bypass (Roux-en-Y) N=136036	Adjustable Gastric Banding N=116898	Sleeve Gastrectomy N=15964
Readmission	6291 (4.62%)	1611 (1.38%)	576 (3.61%)
Reoperation	3710 (2.73%)	759 (0.65%)	272 (1.70%)
Index Length of Stay (days)			
Mean(SD)	2.3 (2.04)	0.7 (1.01)	1.9 (1.94)

EFFICACY: GASTRIC BYPASS>SLEEVE GASTRECTOMY>GASTRIC BAND

In addition to assessing safety, efficacy must be taken into account. The main outcome for efficacy is weight loss. We are aware that weight loss closely tracks comorbidity resolution and subsequent survival benefit. As is demonstrated below in Table 2, the One-Year BMI reduction for the Sleeve Gastrectomy is more than Gastric Banding and slightly less than Gastric Bypass.

Table 2, One-Year Post-Operative BMI Reductions, BOLD 2007-2010

	Gastric Bypass (Roux-en-Y) N=136036	Adjustable Gastric Banding N=116898	Sleeve Gastrectomy N=15964
Body Mass Index (kg/m ²)			
Mean(SD), Pre-op	47.7 (7.90)	45.1 (6.64)	47.5 (9.01)
1 Year Post-op	31.2 (6.24)	37.5 (6.65)	34.1 (8.07)

SPECIFIC MEDICARE BENEFICIARY OUTCOMES: AGE<65 VS >65 LAPAROSCOPIC SLEEVE GASTRECTOMY COMPARABLE SAFETY AND EFFICACY

A current qualification for Medicare coverage includes age> 65. In examining this specific and Medicare relevant population, the safety and efficacy outcomes were equivalent for laparoscopic sleeve gastrectomy in ages >65 and <65. Equally low rates of 30-day morbidity and mortality were seen for both groups with very similar, large reductions in BMI at one year post-operatively in Table 3.

Table 3: 30-Day Outcomes by Age, BOLD 2007-2010

Laparoscopic Sleeve Gastrectomy		
	<65 N=15445	65+ N=519
Deaths	11 (0.07%)	2 (0.39%)
Serious Complications	146 (0.95%)	8 (1.54%)
Any Complications	1298 (8.40%)	38 (7.32%)
Readmission	564 (3.65%)	12 (2.31%)
Reoperation	265 (1.72%)	7 (1.35%)
Body Mass Index (kg/m ²)		
Mean(SD), Pre-op	47.6 (9.05)	46.1 (7.80)
1 year Post-op	34.1 (8.11)	35.1 (7.06)

LEVEL 1 EVIDENCE FOR SLEEVE GASTRECTOMY

There are multiple prospective randomized comparative trials for the vertical sleeve gastrectomy. As seen in table 4, the vertical sleeve gastrectomy compares very favorably to the two CMS-approved procedures. In these comparative effectiveness trials, the weight loss seen with the vertical sleeve gastrectomy exceeds gastric banding and is near equivalent to gastric bypass.

Table 4, Summary of RCTs Comparing Sleeve Gastrectomy to Gastric Bypass or Gastric Banding

Author	Procedures	Follow-up	Weight Loss
Woelnerhanssen et al.	LSG vs. LRYGB	12 months	LSG 28% TBW LRYGB 35% TBW
Kehagias et al.	LSG vs. LRYGB	36 months	LSG 68% EWL LRYGB 62% EWL
Karamanacos et al.	LSG vs. LRYGB	12 months	LSG 69% EWL LRYGB 60% EWL
Himpens et al.	LSG vs. LAGB	36 months	LSG 66% EWL LAGB 48% EWL
Peterli et al.	LSG vs. LRYGB	3 months	LSG 39% EWL LRYGB 43% EWL

Legend: LSG (laparoscopic sleeve gastrectomy), LRYGB (laparoscopic roux-en Y gastric bypass), LAGB (laparoscopic gastric band), EWL (excess weight loss), TBW (total body weight)

The Vertical Sleeve Gastrectomy is a unique surgical intervention appropriate for at-risk patient populations.

Obesity affects over 60% of the national population with approximately 15 million people who qualify for weight loss surgery. Currently, the only effective and enduring treatment for severe obesity is bariatric surgery. With previous National Care

Determinations, CMS has recognized the utility of gastric bypass and gastric banding. With these currently covered operations having sterling safety and efficacy profiles, the vertical sleeve gastrectomy offers another safe and effective therapy for patients in need.

Some potential advantages for the vertical sleeve gastrectomy include maintenance of gastrointestinal continuity with an intact pylorus which affords the premise of appropriate gastrointestinal transit with usual absorption of medications and continued ease of upper endoscopy, all without an implantable device. While the VSG is partly considered a restrictive procedure, the mechanisms of weight loss and improvement in comorbidities seen after VSG may also be related to neurohumoral changes related to gastric resection or expedited nutrient transport into the small bowel. **The neurohormonal changes seen in VSG include early and progressive improvement in insulin sensitivity (insulin, GLP-1, PYY), adipokines (adiponectin, leptin), and satiety (Ghrelin)** (Karamanakos, Ann Surg 2008 & Peterli, Ann Surg 2009).

In addition, it appears the vertical sleeve gastrectomy has lower incidence of both peptic ulcers and nutritional deficiencies (Kehagis, *Obesity Surgery*, 2011 and Gehr, *Obesity Surgery*, 2010). All of these particular advantages of the Vertical Sleeve Gastrectomy hold import for select groups of Medicare patients who require normal absorption of needed medications (Transplant patients), endoscopic surveillance (Prior Gastrointestinal Reconstructive Surgical patients), and routine use of NSAIDS (Arthritis patients).

The Vertical Sleeve Gastrectomy is routinely covered by other payors.

We applaud the CMS reconsideration to include vertical sleeve gastrectomy as a covered benefit. The potential coverage decision will be in keeping with other payors and organizations and allows us to offer the same treatment to Medicare patients that other patients already enjoy.

For example, effective January 2010, the American Medical Association assigned a Current Procedural Terminology code to describe LSG as a primary single-stage restrictive weight loss procedure. Recently, on October 1, 2011, CMS decided to assign Laparoscopic Sleeve Gastrectomy to ICD 43.82 and Open Sleeve Gastrectomy to ICD 43.89. We appreciate CMS's decision that provides for both of these ICD-9 codes to be grouped to DRG 619, 620 and 621, OR procedures for obesity.

Beyond this regulatory recognition, an overwhelming number of payors have chosen to provide vertical sleeve gastrectomy coverage to their beneficiaries. **In sum, current national coverage for vertical sleeve gastrectomy extends to over 104 million patients.** The long list of payors providing vertical sleeve gastrectomy coverage includes, but is not limited to the following: Aetna; Amerihealth; BC/BS Arkansas; BC/BS Nebraska; BS California; CareFirst BC/BS; Cigna; Emblem Health; Excellus BC/BS;

HCSC (parent company for BC/BS Texas, Oklahoma, New Mexico, and Illinois); HealthNet; HMSA (BC/BS HI); Horizon BC/BS New Jersey; Federal BC/BS; Independence BC; BC/BS Texas; Medica; Michigan-BC/BS; Neighborhood Health Plan; Priority Health; QualCare; United Healthcare.

Conclusion

We believe the health outcomes evidence for the vertical sleeve gastrectomy is overwhelmingly favorable and clearly meets the indications listed in the current Bariatric Surgery for the Treatment of Morbid Obesity National Coverage Determination. The vertical sleeve gastrectomy is safe, effective and comparable to the current CMS approved bariatric surgery procedures. We urge its inclusion as a covered benefit so Medicare patients may equally profit with other insured obese patients. We welcome any and all opportunities to discuss this further with you as we all continue in our shared mission of providing optimal, safe, and effective care for our obese patients.

Sincerely,

American Society for Metabolic and Bariatric Surgery

A handwritten signature in cursive script that reads "Robin Blackstone".

Robin Blackstone, MD
President

A handwritten signature in cursive script that reads "Jaime Ponce".

Jaime Ponce, MD
President-Elect



Ninh Nguyen, MD
Secretary-Treasurer



John Morton, MD, MPH
Chair, Access to Care Committee

Stacy Brethauer, MD
Chair, Clinical Issues Committee