



April 23, 2012

Louis Jacques, MD Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
Mail Stop S3-02-017500 Security Boulevard
Baltimore, Maryland 21244-1850

RE: ASMBS Response to CMS Sleeve Coverage Decision

Dear Dr. Jacques:

The American Society of Metabolic and Bariatric Surgery would like to respond to your recent Proposed Decision Memo for Bariatric Surgery for the Treatment of Morbid Obesity (CAG-00250R2). We are concerned that the proposed decision memo reached its conclusions with an incomplete review of available evidence, lack of generalizability to the entire Medicare population, diminished access to care for vulnerable populations and no prior precedence for the level of review and scope of remedy. In addition, we believe the proposed remedy for coverage involving a randomized control trial for laparoscopic sleeve gastrectomy (LSG) is redundant, cost-ineffective and in conflict with CMS published standards of scientific integrity and relevance. We ask you to review the contents of this letter carefully and come to the appropriate conclusion that CMS provide laparoscopic vertical sleeve gastrectomy as a covered benefit. We hope you agree that Medicare beneficiaries should receive the same level of obesity treatment coverage as over 100 million other Americans enjoy.

I. CLARIFICATION OF EVIDENCE

In the proposed decision memo, it is described that there are little either randomized trial or long-term data to support coverage for LSG. Since your literature review end date of 12/2011, several clinical studies on sleeve gastrectomy have recently been

published including 2 randomized trials and 1 prospective cohort study. These studies provide clear and compelling evidence that the laparoscopic vertical sleeve gastrectomy is safe and effective on a randomized trial basis with both medical therapy and CMS-covered bariatric surgeries as controls.

Specifically, the studies include:

- A. In the March 26, 2012 issue of the ***New England Journal of Medicine***, Schauer et al published “*Bariatric Surgery versus Intensive Medical Therapy in Obese Patients with Diabetes.*” In this randomized controlled trial, the efficacy of intensive medical therapy alone versus Roux-en-Y gastric bypass or sleeve gastrectomy in 150 obese patients with uncontrolled type 2 diabetes was performed. The results were enlightening. In this specific population, both bariatric surgeries out-performed intensive medical therapy in a convincing fashion. Also, of note, the sleeve gastrectomy outcomes were equivalent to Roux-en-Y gastric bypass, a CMS covered surgical benefit. At the end of the one-year trial, hemoglobin A1C was 7.5 for intensive medical therapy, 6.4 for Roux-en-Y gastric bypass, and 6.6 for sleeve gastrectomy. As expected, weight loss outcomes had similar results namely, an end-point BMI of 34.4 for intensive medical therapy, 26.8 for Roux-en-Y gastric bypass, and 27.2 for sleeve gastrectomy. Of note, when examining serious adverse events requiring hospitalizations, intensive medical therapy and sleeve gastrectomy hospitalizations were equivalent! (9 vs. 8 %, respectively). This trial was published in the ***New England Journal of Medicine***, which leads all general medical journals in its impact factor. There is no question that this trial is of the highest methodological quality and should be part of the External Technology Assessment of the proposed decision memo.
- B. In the April 16, 2012 issue of the ***Archives of Surgery***, Leonetti and colleagues published *Obesity, Type 2 Diabetes Mellitus, and Other Comorbidities: A Prospective Cohort Study of Laparoscopic Sleeve Gastrectomy vs. Medical Treatment*. From trial initiation to trial end at 18 months, the medical treatment

control group gained weight and saw modest declines in Fasting Plasma Glucose (BMI, 39 to 39.8; FPG, 183 to 150). In contradistinction, the Laparoscopic Sleeve Gastrectomy treatment group saw substantial declines in both weight and Fasting Plasma Glucose (BMI, 41.3 to 28.3; FPG, 166 to 97). Cardiac risk factor assessment showed consistent superiority of Laparoscopic Sleeve Gastrectomy over medical therapy particularly for Triglycerides (LSG, 169 to 97; Medical, 199 to 173).

- C. In the April 2012 issue of **Surgical Endoscopy**, Helmio et al published *SLEEVEPASS: A randomized prospective multicenter study comparing laparoscopic sleeve gastrectomy and gastric bypass in the treatment of morbid obesity: preliminary results*. In this study of 240 patients, early safety outcomes for the sleeve gastrectomy were superior to Roux-en-Y gastric bypass with no mortalities in either group. Overall morbidity was significantly less after sleeve vs. bypass (13.2% vs. 26.5%, $p=0.01$).
- D. The decision memo cites the Himpens 2006 study as meeting criteria for support of the coverage decision and notes need for longer-term follow-up. However, the proposed decision memo excludes the long-term follow up study published by Himpens in **Annals of Surgery** 2010. This six- year study demonstrates durability of the three year results originally presented in **Obesity Surgery** 2006 with a 53.3 % Excess Weight Loss at six years. Three-year results were also presented by Kehagias and colleagues in **Obesity Surgery** 2011 with a 68% Excess Weight Loss. Long-term results are also present in **Obesity Surgery** 2012 where Prasad et al published *An Analysis of 1–3-Year Follow-up Results of Laparoscopic Sleeve Gastrectomy* demonstrating longevity of results with 66% Excess Weight Loss at three years.

II. GENERALIZABILITY TO MEDICARE POPULATION

The Proposed Decision Memo focuses on exclusively on Medicare beneficiaries whose

age is >65. This emphasis on a single population ignores other Medicare beneficiaries whose age is <65 such as patients who are disabled, have End-Stage Renal Disease or beneficiaries who are dual eligible for both Medicare and Medicaid. The over-all Medicare population aged <65 is conservatively at least 20% of the over-all Medicare population (Mathematica Policy Research, May 2001, Volume 2). In our previous October 2011 letter in support of coverage for laparoscopic sleeve gastrectomy, for patients aged less than 65, we cited published studies in NEJM 2009 (Flum), JAMA 2010 (Birkmeyer), Annals of Surgery 2011 (Hutter) and data from over 268,000 bariatric surgeries in the BOLD registry that overwhelmingly demonstrated that the vertical sleeve gastrectomy was positioned exactly between the two covered bariatric surgeries of gastric band and gastric bypass for both complications and weight loss. Furthermore, the disabled Medicare population age<65 is disproportionately at risk for being or becoming obese. Similarly, ESRD disease patients age<65 are at risk for becoming obese and may be disenfranchised from kidney transplantation because of their weight. LSG affords an additional weight loss alternative to the morbidly obese renal failure patient seeking transplantation that non-Medicare patients currently enjoy.

Medicare beneficiaries tend to be a group of patient with higher operative risks. Sleeve gastrectomy is associated with lower morbidity with equivalency in weight loss and resolution of comorbidities compared to gastric bypass. Therefore, sleeve gastrectomy should be an available surgical option for this group of high-risk patient.

According to CMS's own MedPAR data for 2010, we have the following observations about Medicare patients that have bariatric surgery:

1. About 14,500 Medicare beneficiaries had a bariatric surgery procedure in 2010. This represents about 0.04% of all Medicare beneficiaries.
2. 32% (or 4600 beneficiaries) were age >65 and half of them received the band. Note that the morbidity rates for all bariatric patients under Medicare are no different than complication rates for other common surgical procedure such as colectomy, hysterectomy and cholecystectomy.

3. 68% (or 9900 beneficiaries) were age <65, and 70% of these patients were between the ages of 45-64 which is the typical bariatric surgery patient age in the general population.
4. About 600 Medicare patients have already received a lap sleeve gastrectomy in 2010.

Source: Direct Research, LLC, Calculated from FY 2010 Medicare Provider Analysis and Review (MedPAR), Fee-for-Service Inpatient Discharges With Selected Procedures.

The Proposed Decision Memo also states that there are little data for patients older than 65. Given CMS's lack of coverage for LSG in patients >65 years of age, it is not surprising that data may not be as prominent as it is for LSG patients <65. However, there are three studies which demonstrate that laparoscopic sleeve gastrectomy results seen in patients <65 can be replicated in patients >65.

A. Ramirez and colleagues published *Outcomes of Bariatric Surgery in Patients over 70 years of Age* in **SOARD** 2012. This study demonstrated 55% reduction in all medications with no mortalities for all three represented surgeries of banding, bypass and sleeve gastrectomy.

B. Specific to laparoscopic sleeve gastrectomy, Leivonen and colleagues demonstrated in *Laparoscopic Sleeve Gastrectomy in Patients over 59 Years: Early Recovery and 12-Month Follow-Up* in **Obesity Surgery** 2011 that patients older than 60 years of age compared to patients younger than 60 years of age had similar weight loss and no mortality in either group.

C. O'Keefe et al in *Bariatric Surgery Outcomes in Patients Aged 65 Years and Older at an American Society for Metabolic and Bariatric Surgery Center of Excellence* published in **Obesity Surgery** 2010 found that all three weight loss surgeries (band, bypass, sleeve) were effective in patients ≥65 years of age, producing significant EWL, reduction in daily medication use, and improvement in QOL. All surgeries also associated with a Zero 30 day-mortality rate and a low morbidity profile.

D. Finally, 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. We specifically reviewed comparative outcomes for patients age >65 vs. <65 for the three procedures of gastric banding, sleeve gastrectomy and gastric bypass. These findings will be presented at the 2012 American Society of Metabolic and Bariatric Surgeons Annual Meeting this June.

14,476 patients who underwent bariatric surgery between June 2007 and Dec 2010 were aged > 65 were identified. Compared to younger LSG patients, those aged >65 were more often male (39.9% vs. 25.4%), had a higher prevalence of diabetes (47.2% vs. 22.2%), hypertension (73.8% vs. 43.7%), CHF (6.0% vs. 1.7%) and a history of VTE (4.8% vs. 2.5%). Patients aged > 65 undergoing LRYGB had a similar risk profile as older LSG patients. The 30-day mortality rate for older LSG patients was higher than that of younger LSG patients (0.39% vs. 0.07%) as was the rate of serious complications (1.54% vs. 0.95%), however both rates were lower than that seen in age>65 LRYGB patients (0.50% and 2.84%, respectively). Comparatively, LSG patients aged > 65 experienced less morbidity and mortality than older LRYGB patients.

III. PROPOSED REMEDY

The proposal for coverage within a randomized control trial is in conflict with the cited CMS standards of scientific integrity namely categories C-E.

C. The research study does not unjustifiably duplicate existing studies.

Clearly, the call for a randomized control trial for laparoscopic sleeve gastrectomy does duplicate previous studies namely the NEJM STAMPEDE trial cited earlier in I.A. There are also four other randomized control trials answering the same question of whether sleeve gastrectomy is safe and effective in the affirmative (Helmio 2012, Peterli 2012, Karamanakos 2011, Himpens 2010).

D. The research study design is appropriate to answer the research question being asked in the study.

The proposed decision memo does not address what should be an appropriate control group, i.e., medical therapy or comparative surgical therapy. Given the current, limited effectiveness of medical therapy for this group of morbidly obese patients meeting surgical criteria, the next choice for a control group would be comparative surgical therapy. With five randomized trials and almost 300,000 bariatric surgery registry patients supporting the conclusion that sleeve gastrectomy is comparable to banding and bypass for safety and efficacy, the scientific standard should be that the procedure is at least as safe and effective and substantially equivalent to existing covered procedures similar to a 510 (k) submission to the FDA. The proposed randomized trial design is not optimal or even appropriate for determination of the incidence of infrequent complications over a period of years. A RCT for laparoscopic sleeve gastrectomy for age >65 beneficiaries is unnecessarily costly and an inefficient use of resources for such a small patient numbers (<5000 pts.).

E. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.

It is not clear who will be administering the proposed study, who will approve each site, who will monitor adverse events, or propose a data collection model.

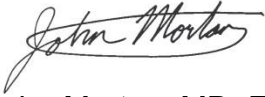
Conclusion

Given that the proposed decision memo did not include vital evidence, we are asking that CMS review the new evidence and reach the fitting and proper conclusion that laparoscopic sleeve gastrectomy become a covered benefit for Medicare beneficiaries who are in need and desirous of the same treatment options as other Americans. We look forward to your reply and welcome an opportunity to meet with you as soon as possible.

Sincerely,

A handwritten signature in black ink that reads "Robin Blackstone". The signature is written in a cursive style with a large, stylized 'R' and 'B'.

Robin Blackstone, MD, FACS, FASMBS
President, American Society for Metabolic and Bariatric Surgery

A handwritten signature in black ink that reads "John Morton". The signature is written in a cursive style with a large, stylized 'J' and 'M'.

John Morton, MD, FACS, FASMBS
Access to Care Chair, American Society for Metabolic and Bariatric Surgery