ASMBS American Society for Metabolic & Bariatric Surgery

April 27, 2012

Louis Jacques, MD
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
Mail Stop S3-02-01
7500 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 carefully and come to the more appropriate conclusion that CMS provide laparoscopic 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 stated 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 two randomized trials and one 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 a published "*Bariatric Surgery versus Intensive Medical Therapy in Obese Patients with Diabetes."* In this randomized controlled trial, the efficacy of intensive medical diabetes management alone versus laparoscopic 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, 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 diabetes management, 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 (kg/m^2) of 34.4 for intensive medical diabetes management, 26.8 for Roux-en-Y gastric bypass, and 27.2 for sleeve gastrectomy. Of note, when examining serious adverse events requiring hospitalizations, <u>intensive medical diabetes management and sleeve gastrectomy hospitalizations were equivalent!</u> (9 vs. 8 %, respectively). This trial was published in the ***New England Journal of Medicine***, which leads <u>*all*</u> 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 kg/m^2) and saw modest declines in Fasting Plasma Glucose (FPG) (183 to 150 mg/dL). In contradistinction, the LSG group saw substantial declines in both weight, BMI 41.3 to 28.3 kg/m^2) and FPG (166 to 97 mg/dL). Cardiac risk factor assessment showed consistent superiority of Laparoscopic Sleeve Gastrectomy over medical therapy particularly for Triglycerides, mg/dl (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 deaths 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 et al. 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 et al. in ***Annals of Surgery*** in 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 (EWL) at six years. Three-year results were also presented by Kehagias and colleagues in ***Obesity Surgery*** 2011 with a 68% EWL. 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% EWL 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 and 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 <65, we cited published studies in ***NEJM*** 2009 (Flum et al.), ***JAMA*** 2010 (Birkmeyer et al.), ***Annals of Surgery*** 2011 (Hutter et al.) and data from over 268,000 bariatric surgeries in the BOLD registry that overwhelmingly demonstrated that the laparoscopic 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 with significantly more comorbidities than the average bariatric population or, in general, they would not have been categorized as disabled. Similarly, ESRD patients age <65 may be disenfranchised from kidney transplantation because of their weight. In addition, the Medicare SSI (disability) population represents a very high-risk group who would benefit from the LSG as a lower risk procedure than RYGB, which is currently covered by CMS. Coverage of the LSG could lower the total cost of management of the high risk Medicare patient (such as those with obesity hypoventilation syndrome, chronic congestive heart failure (CHF), re- or post transplant patients), while providing a more effective procedure, especially for T2DM, than the gastric band, also covered by CMS. The laparoscopic gastric band was never required to show efficacy in RCTs with other bariatric surgical procedures in the CMS population nor show data longer than three-year follow-up when approved by the Food and Drug Administration and then accepted by CMS as a covered procedure.

According to CMS's own MedPAR data for 2010, we have the following observations about Medicare patients that have had bariatric surgery. Namely, bariatric surgery in Medicare beneficiaries is rare with 14,500 Medicare beneficiaries having a bariatric surgery procedure in 2010 representing only about 0.04% of all Medicare beneficiaries. Bariatric surgery in Medicare beneficiaries occurs most commonly in age <65 with 68% (or 9900 beneficiaries) of Medicare bariatric patients 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. Of note, about 600 Medicare patients have already received a laparoscopic 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 deaths 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 <60 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 December 2010 and 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 Venous Thromboembolism (VTE) disease (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 et al. 2012, Peterli et al. 2012, Karamanakos et al. 2011, Himpens et al. 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, adjustable gastric banding, or Roux-en-Y gastric bypass. As standards of care already exist regarding candidacy for bariatric surgery, comparing Sleeve Gastrectomy to medical therapy will not address the real question of whether Sleeve Gastrectomy is an acceptable option to other bariatric surgery procedures in terms of safety and efficacy. With five randomized trials and almost 300,000 bariatric surgery registry patients supporting the conclusion that sleeve gastrectomy is comparable to other bariatric surgery procedures 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 <u>age >65</u> beneficiaries is unnecessarily costly and an inefficient use of resources for such a small patient population (<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 all 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,

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cc: President Barack Obama
Secretary Kathleen Sebelius