Final Comments for Bariatric Surgery for Obesity (GSURG-042) L32904

Comment
Many providers agreed that there is limited medical literature available that specifically supports the LSG in adults over 61 years of age. However, all providers who reviewed L32904 stated that there are patients over 61 years old for whom this is their only option and/or for whom this is their *best* option. Many said they found Laparoscopic Sleeve Gastrectomy, a stand alone operation, to be considered as equal to the Laparoscopic Roux-en-Y gastric bypass in results and better tolerated than any other stand alone operation,

Response:
After careful evaluation of all literature and having multiple discussions with bariatric surgeons and other interested parties, WPS Medicare, in an effort to assure access when medically necessary, has removed any age limitations for the sleeve gastrectomy surgical procedure from policy L32904.

Comment:
Several providers cited as supporting evidence for the LSG for patients older than 61 years of age, the American Society for Metabolic and Bariatric Surgery (ASMBS) findings for LSG:

> According to the American Society for Metabolic and Bariatric Surgery (ASMBS):
>
> 1. The Medicare population is at risk for obesity and its consequences.
> 2. The sleeve gastrectomy is safe and effective and comparable to CMS covered gastric bypass and adjustable gastric banding.
> 3. The sleeve gastrectomy is a unique surgical intervention appropriate for at-risk patient populations.
> 4. The sleeve gastrectomy is routinely covered by ALL other payers.

Response:
WPS Medicare appreciates the efforts of the ASMBS and agrees with their conclusion.

Comment:
Several published articles were submitted and reviewed

Response:
All articles and literature submitted was reviewed by the WPS Medicare CMDs.

Comment:
A few providers offered the following rationale for LSG over the Roux en Y gastric bypass.

> Reasons that a patient may NOT be a candidate for the Roux en Y gastric bypass or gastric banding surgical options:
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> 1. History of abdominal surgeries
> 2. Ulcer disease
> 3. Psychological dysfunction requiring certain medications.
> 4. Blood thinners,

5. Crohn's Disease
6. Autoimmune disease
7. Mild liver disease
8. Previous small bowel resection, previous colon resection, and primary diseases of the small bowel or colon (including ulcerative colitis

Response:
WPS Medicare agrees that the above mentioned medical conditions present additional surgical challenges.

Comment: A physician noted that the absence of studies does not mean the procedure is not safe and effective and stated;

> If these procedures are being performed on this population and no studies, how does the contractor decide whether or not it is medically reasonable? Sure it is being done on patients older than 60 years old, if they are in good health and may live to be age 80 it is being done but they didn't do studies. If it is being done but no studies supporting it how do you decide?

Response:
WPS Medicare agrees that the absence of studies doe not mean that the procedure is unsafe and/or not effective. However, national regulations require that decisions for Medicare coverage are based on clinical evidence that a procedure is safe and effective.

Comment
The following comments from bariatric surgeons were received and given consideration:

> 1. I have first hand experience of the beneficial effects laparoscopic sleeve gastrectomy has on my patients. Their weight lost has been just as good as the lap gastric bypass with fewer postoperative complications and morbidities.
>
> 2. Sleeve gastrectomy has been demonstrated to be a safe and effective bariatric and metabolic operation. It has less complications and risks than gastric bypass (a covered bariatric/metabolic surgery) but similar weight loss. Sleeve gastrectomy has much better weight loss and remission of medical co-morbidities than adjustable gastric banding (a covered bariatric surgery). Thus the results of sleeve gastrectomy lie in between gastric bypass and adjustable gastric banding but are closer to gastric bypass. Furthermore there are particular patients for whom sleeve gastrectomy is ideally suited for and for which the other two covered bariatric operations are not. These include patients who need weight loss outcomes similar to gastric bypass but need future gastric or duodenal surveillance, or have prior abdominal surgery or large ventral hernias with significant intestinal adhesions which would necessitate an open operation with significantly higher complication rates of intestinal injury during dissection as well as increased risks of venous thromboembolism, wound infections, wound hernias, pain, and prolonged recovery. Also, since gastric bypass is an ulcerogenic operation patients who require long-term use of non-steroidal anti-inflammatory agents, steroids, or aspirin are at high risk of complications from ulcers. Sleeve gastrectomy does not increase the risk of ulcerations and thus is a much safer option in these patients.

This includes transplant candidates for whom long term immunosuppression including the use of steroids is frequently needed. Finally, there are certain patients for whom gastric bypass and adjustable gastric banding are contraindicated and sleeve gastrectomy is the only option and this includes patients with Crohn's disease.

3. Ninety percent of my patients now choose the sleeve gastrectomy as their source as a tool for weight loss. I personally have performed over 800 of these procedures and over 100 procedures on patients 65 or older. My results will not be able to be published before you make the decision on coverage, but the early results show that the procedure is safe and effective in the age over 65 population. The excess weight loss in this age group in 54% and there have been no deaths and no major complications.

5. The results for sleeve gastrectomy are no different in the over 61 year's age group than if they had a Band or Bypass or any other surgery. You do not discriminate any other procedure because of age. The risks of surgery are much less than staying obese and not having surgery. Overall, more serious complications are less with the sleeve than the bypass. The weight loss with the sleeve is within 5%-10% of that of the bypass. Age is not a factor. While it is true that older patients have higher risks for any surgery, there is no other surgery that CMS would not approve just because of age.

5. Bariatric surgery has been demonstrated to be a safe procedure in the Medicare population. When deciding on surgery for a particular patient, we need to make sure that the patient is medically and mentally ready for bariatric surgery. Limiting our decision on which procedure to perform on an individual patient truly does a disservice to that patient. Many patients are not good adjustable band candidates, but performing a gastric bypass may be difficult and lengthy, putting that patient at a higher surgical risk. A sleeve gastrectomy may be a better option and often shorter operation time, decreasing the risk.

6. Sleeve gastrectomy has, over the past five years, demonstrated its superior efficacy for weight loss over and against adjustable banding AND vertical-banded gastroplasty, despite the fact that CMS provides coverage for the latter two procedures. Particularly for patients who are over age 60, sleeve gastectomy provides a level of safety which exceeds that of the bypass, while providing a level of efficacy that far exceeds that of adjustable banding (which, as two studies published five years ago out of Texas—see Provost, David, demonstrate, is not an appropriate option for weight loss in patients over age 60, and yet continues to be covered by CMS). … Medicare patients know that the sleeve gastrectomy procedure can help them (esp. for those over age 60) where the band cannot, know that sleeve gastrectomy can resolve their diabetes with a better safety profile than bypass, and yet currently, if they want a totally appropriate option to address their morbid obesity, they will have to pay cash out of pocket for the

intervention. This despite the fact that they can obtain a less appropriate option (band or vertical-banded gastroplasty) at CMS expense.

Response:
WPS Medicare considered all medical practice experience and reports as valid testimony in the decision to remove age limitation from the LCD.

8. Comment
LCD DL32904 indicates CPT code 43775 is designated status "N" and not paid by Medicare Contractors. However, according to the October 2012 update to the Outpatient Code Editor CPT Code 43775 has been assigned an OPPS status indicator of "C" (Inpatient Only procedure) effective June 27, 2012. We request WPS update the language in the draft LCD accordingly.

Response:
WPS Medicare has revised the LCD, changing the status of CPT code 43775 from "N" to "C".

Comment:
A surgeon cited studies and recent presentations as evidence to remove age restrictions form the policy:

Studies were presented at the 29th Annual Meeting of the American Society for Metabolic & Bariatric Surgery (ASMBS) from Stanford University, Cleveland Clinic Florida and the Naval Medical Center in San Diego that show laparoscopic sleeve gastrectomy is as safe as or safer than laparoscopic gastric bypass or gastric banding.
Additional studies cited included in this review included:

1. A study done by Eid, Brethauer, Mattar, Titchner, Gourash and Schauer at the Department of Veterans Affairs, Pittsburgh Healthcare System1, reviewed patients of ages up to 78 years of age. Perioperative mortality was zero and the incidence of short- and long-term postoperative complications was 15%. The mean BMI decreased from 66kg/m to 46 kg/m and 77% of the diabetic patients showed improvement or remission of diabetes. This study reported that laparoscopic Sleeve Gastrectomy was effective and safe, even in high-risk, high-BMI patients, regardless of age.

2. A study done by Leivonen, Juuti, Jaser and Mustonen at the Department of Surgery at Helsinki University Central Hospital2, showed that Bariatric surgery is safe for patients over 60 years of age with the highlight being the resolution of co morbid conditions. In this study, they compared patients over 59 years of age to those less than 59 years of age. There were no deaths, and excess weight loss and resolution of co morbidities after 12 months was comparable between these two groups. They concluded that Sleeve Gastrectomy is safe and effective for older Bariatric patients with the same good results as with a younger population.

3. A study done by Gluck, Movitz, Jansma, Gluck and Laskowski at Mercy Health Partners in Muskegon, Michigan3 included patients with an age range up

to 70 years. Again weight loss was good, operative complications were 1% or less and again, the results of the study showed excellent outcomes regardless of age.

4. A study by Buesing, Utech, Halter, Riege, Saada and Knapp at the Klinik fur Allgemain und Viszeralchirurgie in Recklinghausen, Germany4, included patients up to 72 years of age. 197 patients out of 200 had their procedures without complications and in 45 of the 70 diabetics, their medication was stopped three months after the surgery. Again, they concluded that Sleeve Gastrectomy appears to be an effective surgical option for the treatment of morbid obesity with a low complication rate, regardless of age.

5. At the Department of Surgery at the Grand Rapids Medical Education and Research Center in Michigan, O'Keefe, Kemmeter and Kemmeter conducted a study5 on patients specifically of 65 years and older stating in the study that obesity in this population was on the rise! Their evaluation included mortality rates, length of stay, amount of weight lost, change in co morbid conditions, quality of life. They found that, on average, weight, BMI and daily medication use were significantly reduced at six months and at one year. The mortality rate was 0% at 30 days and only 1.3% at one year (for Gastric Bypass patients, only).

6. A study done by Arias, Martinez, Ka Ming Li, Szomstein and Rosenthal at The Bariatric and Metabolic Institute at the Cleveland Clinic in Florida6, covered patients ranging in age up to 79 with 0% mortality and a complication of 2.1% or less. They concluded that Lap Sleeve Gastrectomy was safe and effective, regardless of age.

Response:
WPS Medicare appreciates your comprehensive review of the policy and providing studies related to the sleeve gastrectomy surgical procedure. .

Comment:
A bariatric surgeon informed WPS Medicare of the following;

The article "The Comparative Effectiveness of Sleeve Gastrectomy, Gastric Bypass, and Adjustable Gastric Banding Procedures for the Treatment of Morbid Obesity" (manuscript # ANNSURG-D-12-01039R2) is now officially "in print" and accepted for publication by the Annals of Surgery.
The Executive Members of the Michigan and Indiana ASMBS State Chapters are requesting that you now consider the data from the MBSC publication in your final decision analysis. The MBSC data clearly positions sleeve gastrectomy outcomes between the gastric bypass and gastric band throughout *all* age groups. The comparative effectiveness analysis, with evenly matched cohorts (almost 3000 patients per cohort), provides convincing and conclusive data that sleeve gastrectomy is a safe and effective procedure. .

Response:
WPS Medicare reviewed the above article.

Comment:
A bariatric nurse questioned the usefulness of the body mass index (BMI)
Response:
The criteria for body mass index (BMI) coverage is determined by CMS.

Comment:
Several comments and a few good outcome testimonies from interested individual were received asking for removal of age limitations within the LCD.
Response:
WPS Medicare sincerely thanks all interested parties, particularly our beneficiaries, who took the time to review and comment on the bariatric surgery policy.