Washington State Health Care Authority

Health Technology Assessment

Bariatric Surgery

Draft Key Questions: Comment & Response

November 7, 2014

Health Technology Assessment Program (HTA)
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Bariatric Surgery

Key Questions
Public Comments and Response

November 7, 2014

Response to Public Comments

The Institute for Clinical and Economic Review (ICER) is an independent vendor contracted to produce evidence assessment reports for the Washington Health Technology Assessment (HTA) program. For transparency, all comments received during the public comment period are included in this response document. Comments related to program decisions, process, or other matters not pertaining specifically to the draft key questions, project scope, or evidence assessment are acknowledged through inclusion only.

This document responds to comments from the following parties:

Draft Key Questions

- John de Csepel, MD, FACS, VP Global Medical Affairs, Chief Medical Officer, Advanced Surgical Technologies, Covidien
- Robert Michaelson, MD, PhD, FACS, ASMBS, NW Weight Loss Surgery, President, ASMBS Diplomate, American Board of Obesity Medicine, Washington State Chapter – American Society for Metabolic and Bariatric Surgery

	Comment	Response
John de Csepel, MD, FACS, VP Global Medical Affairs, Chief Medical Officer, Advanced Surgical Technologies, Covidien		
1	Given the extensive review of bariatric surgery in the over 65 population to support the Center for Medicare and Medicaid Services' National Coverage Decision, we believe the evidence supporting the benefits of bariatric surgery in the over 65 population has been clearly demonstrated and does not require further review at this time.	*Thank you for your comments and references. No changes to scope or key questions. The NCD for bariatric surgery in the over 65 population only applies only to those with a BMI ≥35kg/m² and at least one comorbidity related to obesity; while the NCD will provide important context for our review, the scope of interest includes patients not covered by the NCD such as those at lower levels of BMI.*
2	We appreciate the need to update the original assessment of bariatric surgery in the pediatric population conducted for the HCA in 2007 in light of new evidence published for this patient population. However, the evidence base for evaluating bariatric surgery in the pediatric population continues to evolve rapidly, and thus it may be premature to conduct a full assessment in this population at the current time. At a minimum, we recommend that the HCA consider providing a clear plan for future updates to the assessment in the pediatric population given the number of ongoing studies and new evidence likely to emerge after publication of this review.	*No changes to scope or key questions. Given the growing acceptability of bariatric surgery as a treatment option for pediatric obesity, we will evaluate the literature that has been published since the 2007 assessment and continue to review the landscape as more evidence becomes available.*
3	…guidelines based on an extensive body of evidence clearly delineate a pathway for the success of bariatric surgery, which includes a combination of services… Moreover, given the design of credible and high quality studies in this area, it is not likely to be methodologically possible to appropriately disaggregate the components of the bariatric surgery intervention. Thus, we recommend that the assessment focus on bariatric surgery interventions in their totality, when provided according to recommended guidelines.	*No changes to key questions. It is not our intention to disaggregate components to determine those that programs should retain; rather, our goal is to identify studies that sought to identify predictors of treatment success across programs and providers, which may include both patient and program factors.*
4	We recommend that the cost effectiveness measures include not only the reduction of healthcare spending due to reduced utilization and comorbidity resolution, but also costs associated with employee productivity measures such as workplace absenteeism.	*We have added language to the background section to indicate that our economic evaluation will include a sensitivity analysis that accounts for the impact of each treatment approach on work productivity.*

Robert Michaelson, MD, PhD, FACS, ASMBS, NW Weight Loss Surgery, President, ASMBS Diplomate, American Board of Obesity Medicine, Washington State Chapter – American Society for Metabolic and Bariatric Surgery		
1	[Key Question 1]: As to the definition of "adult" being age 21 and older; most experts consider patients candidates for bariatric surgery when they are 18 years of age and older. In selected individual circumstances, younger patients may be considered if there is radiographic evidence that growth plates have closed; and psychosocial evaluation reveals they are capable of dealing with the post bariatric surgery lifestyle changes necessary for long-term success.	*Thank you for your comments and references. No changes to key question 1. The rationale to include those 18-20 years old in the adolescent population is driven by the state's need to evaluate findings for its covered populations, the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit that governs all Medicaid programs allows for coverage of health care services for all individuals under age 21.*
2	[Key Question 2]: In 2014, there is no surgeon or surgical practice in Washington that is not affiliated with a Bariatric Center of Excellence (COE). It can be debated as to whether outcomes are better in a COE versus a non-COE program. What is indisputable however, are the requirements for becoming a COE. These are rigorous certification processes requiring that all elements of a comprehensive, multi-disciplinary program are met. Therefore, all of the programs in our state use the NIH Guidelines for patient selection; all involve a multidisciplinary care team; all involve pre and post –procedure counseling and support; all programs make every effort to follow their patients long-term.	*No changes to key question 2. We will assess the available data on all program components associated with bariatric surgery, both collectively and individually. If these variables have been thoroughly studied we will summarize the major conclusions on how and to what extent they impact rates of success. To the extent feasible, we will also characterize any state-specific documentation around bariatric centers of excellence.*
3	[Key Question 3]: There is a prevalent misconception that bariatric surgery is associated with more complications than other surgical procedures. Table 1 summarizes data gathered from Medicare and Medicaid inpatient discharges for patients undergoing the indicated procedures. It is clear from this data that bariatric surgery is no riskier than, and any of the listed surgical procedures, and safer than most… A comparison of this data reveals that the rate of complication increases in proportion to the complexity of the operation. Adjustable gastric banding is the least complicated surgical procedure, followed by sleeve gastrectomy, RYGB and BPD/DS with complication rates of: 4.6%; 10.8%; 14.87%; and 25.65% respectively. It should be noted that these rates are inversely proportional to the weight loss with each procedure (DeMaria et al., 2010).	*No changes to key question 3. We will evaluate the evidence on harms for each of the bariatric procedures germane to this review. We appreciate the suggestion to compare complication rates with those of other major elective surgical procedures, and will seek to make this an important component of our report.*
4	[Key Question 4]: Bariatric surgery has become one of the most commonly performed general surgery procedures and it is almost exclusively performed laparoscopically with a good safety profile (Finks JF, Dimick JB An updated National Institutes of Health Consensus Panel on Bariatric Surgery. JAMA Surgery Published online October 1, 2014). It is very rare for any	*We have removed subcategory (d) (laparoscopic vs. open approach), for consideration from key question 4. However, we will continue to evaluate conversion to open procedures as an outcome of interest for this evaluation.*

Robert Michaelson, MD, PhD, FACS, ASMBS, NW Weight Loss Surgery, President, ASMBS Diplomate, American Board of Obesity Medicine, Washington State Chapter – American Society for Metabolic and Bariatric Surgery		
	bariatric procedure performed in this day and age to be done so as an open procedure primarily. The open approach is generally reserved if difficulties are encountered preventing the progression of a laparoscopic operation. Conversion to an open approach occurred in only 274 of 57,918 bariatric surgical procedures in the BOLD database (De Maria EJ et al. Baseline data from the American Society for Metabolic and Bariatric Surgery-designated Bariatric Surgery Centers of Excellence using the Bariatric Outcomes Longitudinal Database. SOARD 6 (2010) 347-355).	
5	[Key Question 5]: There is ample data in the literature to address these items.	*No changes to key question 5.*
6	[Key Question 6]: With regard to cost effectiveness of bariatric surgery in general, there is data to support both positions that bariatric surgery is cost effective; and that it is not. What is emerging to be a more clear cost benefit analysis is the effect of bariatric surgery on type 2 diabetes over all weight classes from Class I through Class III Obesity…	*No changes to key question 6. We intend to evaluate the economic impact of bariatric surgery vs. conventional weight-loss treatment on all outcomes, including the associated effect on obesity-related comorbidities. This will be done through both a review of the published economic literature as well as the development of a simulation model.*
7	Finally, we feel that current policies for Bariatric Surgery should be reviewed and modified. State employees receiving coverage under the Uniform Plan are assigned a case manager who works with the patient for…	*No changes to scope or key questions. Discussions of current coverage policies are outside the scope of the evidence review.*

COVIDIEN

October 22, 2014

Dorothy F. Teeter, MHA
Director
Washington State Health Care Authority
626 8th Avenue, SE
P.O. Box 42712
Olympia, WA 98504-2712

Submitted via Email: shtap@hca.wa.gov

Dear Ms. Teeter,

Covidien is pleased to submit comments regarding the Draft Key Questions for Washington State Health Care Authority's (HCA) review of ***Bariatric Surgery***.

Covidien is a manufacturer of Medical Devices and Medical Supplies. We provide training in the safe and effective use of our products and related procedures, guided by scientific evidence. In addition to the comments we are submitting here, we fully endorse the comments submitted by professional societies including the American Society for Metabolic and Bariatric Surgery (ASMBS) and the Obesity Action Coalition during the public comment period for these Draft Key Questions.

As noted in our prior comments, obesity is a major public health issue in the United States, and Washington State is no exception. According to the Washington State Department of Health, in 2011, 27% of Washington adults and 25% of Washington children were obese. Studies have demonstrated that obesity results in higher morbidity for a range of health conditions, many of which are on the list of 15 chronic conditions proposed by CMS to be part of the Chronic Conditions Special Needs Plans (Available at: http://www.cms.gov/Medicare/Health-Plans/SpecialNeedsPlans/Chronic-Condition-Special-Need-Plans-C-SNP.html. Accessed April 29, 2014). These include: hypertension, type 2 diabetes, coronary artery disease, stroke, gallbladder disease, osteoarthritis, sleep apnea, respiratory issues, and some types of cancer (endometrial, breast, prostate, and colon). Approximately 75% of people with morbid obesity have at least one comorbid condition – often type 2 diabetes, hypertension, or sleep apnea – which increases the risk of premature death (Must et al, JAMA 1999).

In addition to the clinical burden, obesity represents a significant financial burden on the U.S. and the state of Washington. In 2008, U.S. medical costs linked to obesity were ~$147 billion (~9% of medical spending). Medical costs for obese people were $1,429, which is 42% higher than those of normal weight (Finkelstein et al, Health Aff 2009). The financial burden of obesity on the state of Washington was estimated at $1.13 billion in 2003 (Finkelstein et al, Obes Res 2004).

Given the magnitude of the burden of obesity on the state, it is critical to ensure appropriate access to treatments that have been demonstrated to reduce obesity rates, such as bariatric surgery. Our comments below are provided in this context.

Project Scope

Covidien supports the overall scope of the ***Bariatric Surgery*** technology assessment as outlined in the Draft Key Questions and Background document. However, we suggest the following considerations.

Population

- For the adult population, we continue to suggest that the HCA focus on the under 65 adult population. Given the extensive review of bariatric surgery in the over 65 population to support the Center for Medicare and Medicaid Services' National Coverage Decision, we believe the evidence supporting the benefits of bariatric surgery in the over 65 population has been clearly demonstrated and does not require further review at this time.
- We appreciate the need to update the original assessment of bariatric surgery in the pediatric population conducted for the HCA in 2007 in light of new evidence published for this patient population. However, the evidence base for evaluating bariatric surgery in the pediatric population continues to evolve rapidly, and thus it may be premature to conduct a full assessment in this population at the current time. At a minimum, we recommend that the HCA consider providing a clear plan for future updates to the assessment in the pediatric population given the number of ongoing studies and new evidence likely to emerge after publication of this review.

Intervention and Comparators

- Overall, we support the comparators included in the Draft Key Questions and Background. However, we recommend that the assessment be clearly focused on comparators designed to treat obesity, as opposed to obesity prevention modalities. Many medical programs, including counseling, psychotherapy, etc. are designed for prevention rather than treatment, and studies of programs designed for obesity prevention – in part of in whole - as opposed to treatment should not be included as comparators to bariatric surgery.
- We strongly support the evaluation of combinations of conventional therapies, as specified in the Draft Key Questions and Background document. Guidelines suggest pathways for bariatric surgery that incorporate appropriate pre- and post-procedure counseling, and inclusion of these services along with bariatric surgery can have implications for patient outcomes. It is therefore critical that the assessment distinguish studies in which bariatric surgery was provided consistent with recommended guidelines regarding pre- and post-surgery services, including counseling, medical management, etc.

Outcomes

- We support the outcomes of primary interest described in the Draft Key Questions and Background document.
- In particular, we emphasize the need to include short-term outcome measures related to patient safety, including complication rates, recovery time, infections, etc. as well as longer-term outcomes related to sustained weight loss, change in BMI, revision/reversal, and other measures of long-term morbidity and mortality. These short-term measures are of critical importance to patients and can vary significantly based on modality and thus should be fully evaluated for each treatment modality included in the assessment.
- The Draft Key Questions and Background document states, "Finally, given the interest in documenting specific components of the treatment approach in each study, we will seek to identify those components correlated with higher levels of treatment success." (Washington State Health Care Authority, ***DRAFT Key Questions and Background Bariatric Surgery***, page 4.) While we appreciate the desire to understand the various components of treatment, we note that guidelines based on an extensive body of evidence clearly delineate a pathway for the success of bariatric surgery, which includes a combination of services from pre/post-procedure counseling, pre-operative preparation, post-operative/recovery care, and subsequent follow-up. Trying to disaggregate these services is counterproductive, when the totality of these pathways has been demonstrated to be effective. Moreover, given the design of credible and high quality studies in this area, it is not likely to be methodologically possible to appropriately disaggregate the components of the bariatric surgery intervention. Thus, we recommend that the assessment

focus on bariatric surgery interventions in their totality, when provided according to recommended guidelines.

- In terms of study duration thresholds, we recommend that well run, sufficiently powered studies should receive maximum consideration in the assessment, regardless of study duration.
- We recommend that the cost effectiveness measures include not only the reduction of healthcare spending due to reduced utilization and comorbidity resolution, but also costs associated with employee productivity measures such as workplace absenteeism. Productivity is a key consideration for the economic health of Washington State and should thus be a central component of the economic evaluation of bariatric surgery.

Analytic Framework

- We agree with the Analytic Framework included in the Draft Key Questions and Background document.

Draft Key Questions

We believe the key questions included in the Drat Key Questions and Background document are appropriate. On question 1, we note our comments above regarding the assessment population, and recommend that HCA focus on adults younger than 65. We also reiterate our caution regarding the rapid evolution of the evidence for the pediatric patient population, which is critical context for any recommendations related to this patient group.

As an attachment supplement to these comments, we have provided a brief summary of key evidence addressing each of the six Draft Key Questions. This summary is included as an Attachment to this letter.

Conclusion

In conclusion, the burden of obesity in the U.S. and in the state of Washington is significant and a strong evidence base supports the value of bariatric surgery in reducing this burden for appropriate patients. Morbid obesity is a disease, and individuals suffering with morbid obesity should be provided access to the best treatment options available.

Per our above comments, we encourage the Washington State HCA to focus on the appropriate patient populations and provide appropriate context for the pediatric population, in which the bariatric surgery evidence base is evolving rapidly. We also encourage the HCA to exercise caution in how treatment modalities are parsed for evaluation, with the understanding that successful bariatric surgery outcomes do require appropriate pre and post-operative services. Most importantly, we continue to recommend that the Washington State HCA to rely on the good work conducted by other HTA bodies and the medical/science community, including work by the Centers for Medicare and Medicaid Services and the National Institutes of Health, to inform the assessment.

Regards,

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Vice President of Global Medical Affairs
Chief Medical Officer, Advanced Surgical Technologies
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Supplement:
Evidence Related to Draft Key Questions

1) What is the comparative clinical effectiveness of bariatric surgery versus conventional weight loss management in:

a. **Adults (i.e., age 21 years and older)?**
b. **Children (age <21), overall and by age group (i.e., ≥18 to <21, ≥13 to ≤17, ≤12)?**

A recent National Institutes of Health (NIH) Symposium summarized the long-term outcomes of bariatric surgery compared to nonsurgical treatments. The multidisciplinary workshop discussed several small randomized trials showing greater weight loss and type 2 diabetes mellitus remission in the first two years following bariatric surgery compared to nonsurgical treatments. The symposium also reported on large, long-term observational studies demonstrating sustainable weight loss, diabetes remission, and lipid improvements with surgery (Courcoulas et al., JAMA Surg 2014). In addition to type 2 diabetes mellitus remission, multiple systematic reviews and meta-analyses have shown improvements in obesity-related comorbidities after bariatric surgery, including cardiovascular disease (Vest et al., Heart 2012), hypertension (Sarkhosh et al., Obes Surg 2012), obstructive sleep apnea (Sarkhosh et al., Obes Surg 2013), cancer (Tee et al., Surg Endosc 2013), nonalcoholic fatty liver disease (Mummadi et al., Clin Gastroenterol Hepatol 2008), and osteoarthritis (Gill et al., Obes Reviews 2011). Additionally, studies have pointed to effects of bariatric surgery in improving sexual function (Sarwer et al., JAMA Surg 2013) and intervertebral disc heights (Lidar et al., Spine 2012), and reducing the need for joint replacement procedures (Kulkarni et al., Surgeon 2011).

A review by Wasserman and Inge reports that a number of studies have demonstrated a lack of sustained body mass index (BMI) reduction in obese adolescents after nonsurgical weight loss programs (Wasserman et al., Pediatr Ann 2014). Sugerman et al. report a retrospective analysis of 33 adolescents aged 12-18 (eligible by NIH adult criteria) who underwent bariatric surgery at a single institution. Safety results were acceptable. Two revisions were later required, one for malnutrition and one for weight regain. Significant weight regain was seen in 15%; the remaining 85% maintained weight loss for up to 14 years of follow-up (Sugerman et al., J Gastrointest Surg, 2003). Beyond this small sample, studies have shown that bariatric surgery can lead to weight loss and comorbidity resolution in adolescents in the short-term, although data are limited. In addition, there is little data about long-term consequences after one year (Whitlock et al., Evid Rep Tech Assess 2008).

2) What components of the management of patients undergoing bariatric surgery (e.g., selection of candidates for surgery, multidisciplinary care team, pre- and/or post-procedure counseling and support) appear to be correlated with higher levels of "treatment success" (e.g., sustained weight loss, reduction in comorbidity burden, etc.)?

Patients who attend support groups following bariatric surgery show better weight loss than those who don't (Livhits et al, Obes Reviews 2011; Orth et al, Obes Surg 2008), even after controlling for BMI (Kaiser et al, Surg Obes Rel Dis 2011). A retrospective single-center cohort study has also shown that structured nutritional counseling for patients after bariatric surgery is associated with sustained weight loss (Endevelt et al., Surg Obes Relat Dis 2013).

3) What are the potential short- and long-term harms of bariatric surgery, including rates of procedure-specific and general surgical complications, longer-term morbidity, mortality, and the need for procedure revision and/or reversal?

According to the ASMBS Bariatric Centers of Excellence database of about 60,000 procedures, the risk of death from bariatric surgery is 0.13% (DeMaria et al., Surg Obes Relat Dis 2010). Data from over 25,000 patients in the Michigan Bariatric Surgery Collaborative program showed a mortality rate of 0.1%. The SOS study reported a mortality rate of 0.25% in the surgical cohort within 90 days (Picot et al., Health

Technol Assess 2009). Mortality risk of bariatric surgery is similar to that of hip replacement (0.3%) and is one tenth the mortality risk of coronary artery bypass (Dimick et al., JAMA 2004).

Perioperative risks associated with bariatric surgery include anastomotic and staple line leaks, wound infections, hemorrhage, and pulmonary events. Overall, complication rates are lower following laparoscopic surgery compared to open procedures. The incidence of adverse events increases with surgical complexity; laparoscopic adjustable gastric banding is associated with the lowest rates, followed by sleeve gastrectomy, Roux-en-Y gastric bypass, and biliopancreatic diversion (DeMaria et al., Surg Obes Relat Dis 2010). Long-term concerns include mineral and vitamin deficiencies, especially for bypass and diversion procedures. However, this problem is addressed by dietary guidelines developed by The Obesity Society (TOS), the ASMBS, and the American Association of Clinical Endocrinologists (AACE). Long-term dietary advice is required following all medical interventions for obese patients, including patients not electing to have surgery (Mechanick et al., Surg Obes Relat Dis 2013).

4) What is the differential effectiveness and safety of bariatric surgery according to health-system and/or program factors such as:

- **a. Surgeon experience**
- **b. Procedure volume**
- **c. Type of procedure**
- **d. Laparoscopic vs. open approach**
- **e. Certification of surgery center**
- **f. Members of core team**
- **g. Type of pre-procedure preparation/post-procedure support**

Higher peer-rating of operative skill was associated with fewer postoperative complications and lower rates of reoperations and readmissions (Birkmeyer et al., N Engl J Med 2013).

The Longitudinal Assessment of Bariatric Surgery (LABS) study on gastric bypass highlighted a reduced risk of adverse outcomes associated with increased surgeon case volume per year (Smith et al., Surg Obes Relat Dis 2010). This finding was supported by a systematic review of 24 studies including over 450,000 patients that reported improved patient outcomes in high-volume surgeons/centers (Zevin et al., Ann Surg 2012).

Studies have shown that laparoscopic approaches are associated with shorter surgical time, fewer reoperations, and reduced length of stay compare to open procedures (Tian et al., Obes Reviews 2011; Banka et al., Arch Surg 2012).

In a systematic review of 31 randomized controlled trials, a comparative effectiveness assessment of different bariatric surgical approaches showed that weight losses are greatest with diversionary procedures, intermediate with diversionary / restrictive procedures and lowest with purely restrictive procedures (Padwal et al, Obes Reviews 2011).

Dimick et al. (JAMA 2013) assessed the impact of the Centers for Medicare and Medicaid Services' (CMS) policy to restrict coverage to Centers of Excellence and found no significant differences complication or readmission rates before and after the policy restriction. However, among academic medical centers, accredited centers reported lower in-hospital mortality compared to non-accredited centers. The lower mortality rate was potentially attributed to the ability of the accredited centers to recognize and treat complications (Nguyen et al., J Am Coll Surg 2012).

5) What is the differential effectiveness and safety of bariatric surgery according to patient and/or clinical factors, such as:

a. **Age (both chronological and physiologic/skeletal)**
b. **Gender**
c. **Race/ethnicity**
d. **Pre-operative BMI (assessed as both continuous and categorical variables)**
e. **Presence of comorbidities (e.g., hypertension, Type 2 diabetes)**
f. **Prior event history (e.g., myocardial infarction, stroke)**
g. **Smoking status**
h. **Psychosocial health**

Patient age, race, and gender are also important factors that impact mortality after bariatric surgery. Predictors of greater in-hospital mortality include male gender, gastric bypass (versus banding or gastroplasty) open surgical technique (versus laparoscopic), presence of diabetes, and age >60 (Nguyen et al., Surg Obes Rel Dis 2013). However, in-hospital mortality in elderly patients following bariatric surgery is lower in recent years compared to earlier reports. Gabhart et al. demonstrated mortality rates of 0.11% for the elderly in 1999-2005 compared to 0.05% in 2009-2013; the improved rate is now even better than the mortality rate seen in non-elderly patients in 1999-2005 (Gabhart et al., Surg Obes Rel Dis 2014). In a large Veterans Affairs cohort of primarily severely obese, older white men (mean BMI 47; mean age 49.5 years), bariatric surgery was not associated with decreased propensity-adjusted mortality compared with usual care after a mean of 6.7 years follow-up (Maciejewski et al., JAMA 2011).

The impact of pre-operative BMI on the effectiveness of bariatric surgery has been assessed in multiple studies with the general perspective that the percent excess weight loss (%EWL) is relatively lower for patients with a higher BMI despite the observation that patients in this group lose more total weight. In a recent retrospective analysis of 1,993 patients undergoing either laparoscopic gastric bypass or laparoscopic gastric banding, patients were stratified into one of 4 BMI categories (35-39.9; 40.0-49.9; 50.0-59.9; ≥60) and %EWL was reviewed from 1 month through 36 months of follow-up. For each time point, the %EWL for each BMI category was significantly less than the %EWL for the next lower preoperative BMI category (Ochner et al., Surg Obes Rel Dis 2013).

The incidence of postoperative complications does not appear to differ when comparing super–super-obese patients with BMI ≥60 kg/m^2 to obese patients with BMI ≤60 kg/m^2. Tichansky et al. (Surg Endosc 2005) retrospectively assessed postoperative complications in 45 super–super-obese patients compared to 640 patients with a BMI <60 kg/m^2. There were no statistically significant differences in mortality or complication rates between the two groups. Complications analyzed included anastomotic leaks, internal hernia, incisional hernia, small bowel obstruction, stomal stenosis, and pulmonary embolism. Mean length of stay was somewhat longer for patients in the ≥60 BMI group, but this difference was not significant (P=0.16). Operating time was significantly longer for the ≥60 BMI group (P=0.04) and %EWL was significantly lower (P<0.0001).

Excess weight and obesity are known risk factors for the development of certain types of cancer, and the weight loss associated with bariatric surgery has been shown to decrease this risk. However, a recent meta-analysis by Tee et al. (Surg Endosc 2013) found that when stratified by gender, bariatric surgery is protective against oncologic risk in women but not in men.

Long-term mortality caused by comorbidities is known to be significantly reduced after gastric bypass surgery. Adams et al. (New Engl J Med 2007) found that cause-specific mortality after bariatric surgery decreased by 56% for coronary artery disease, 92% for diabetes, and 60% for cancer.

The impact of psychological and biological measurements (MMPI-2 and other markers) on outcomes following bariatric surgery has been assessed in predictive models; however, these models remain imperfect with significant rates of misprediction (Tsushima et al., Obes Surg 2004; Sarzynski et al., Int J Obes 2011).

In addition to the patient and clinical factors listed above, operative elements may be added as an additional comparator for consideration. Adverse events occurring intraoperatively are of high clinical significance and correlate negatively with patient safety. A prospective study of nearly 6,000 bariatric surgery patients examining the relationship between intraoperative adverse events (including organ injuries, anesthesia-related events, anastomotic revisions, and equipment failure) and 30-day composite index of major adverse complications (death, venous thromboembolism, reintervention, or >30 day hospital stay) showed that patients with an intraoperative adverse event were at 90% greater risk of composite complications than those without an event, independent of the procedure type (Greenstein et al., J Am Coll Surg 2012).

Lemanu et al. (Obes Surg 2012) provided a comprehensive assessment on optimizing perioperative care in bariatric surgery patients. Smoking is associated with increased morbidity and mortality in any type of surgery due to inhibition of the immune system. It has been suggested that patients smoking within 4 weeks of the date of surgery be excluded from surgery or postpone scheduling of surgery. Preoperative weight loss was the only factor associated with postoperative weight loss. Additionally weight loss may help reduce liver volume, thereby enabling better visualization during surgery. Implementation of anorectic supplements have been suggested 2-4 weeks pre-operatively, in addition to an exercise program.

6) What are the costs and cost-effectiveness of the major bariatric surgery procedures of focus in this evidence review?

Based on large database research, it was shown that bariatric surgery could add 2-3 years of additional life expectancy and incremental cost-effectiveness ratios of $6,600 per Quality Adjusted Life Year (QALY), which is well below the accepted threshold of $50,000 per QALY (Wang et al., Eur J Health Econ 2013). The costs of the initial surgery are usually recovered within 2-4 years due to downstream savings in healthcare utilization (Cremieux et al., Am J Manag Care 2008). One of the most exhaustive Health Technology Assessments evaluating clinical and cost-effectiveness established the utility of bariatric surgery compared to nonsurgical interventions among moderately to severely obese people (Picot et al., Health Technol Assess 2009).

Washington State Chapter – American Society for Metabolic and Bariatric Surgery

Initial Response to Washington Health Care Authority – Health Technology Assessment

Bariatric Surgery

WA-ASMBS Board of Directors

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Introduction

The Washington Chapter of the American Society for Metabolic and Bariatric Surgery (WA-ASMBS) appreciates the opportunity to respond to the Draft Key Questions proposed by the WA-HTA. The WA-ASMBS is comprised of Bariatric Surgeons; Bariatric Physicians and the integrated health personnel without whom, comprehensive bariatric surgical programs could not exist. We would like to offer our collective expertise to assist in any way, as the Washington State Health Care Authority reviews its coverage policy for bariatric surgery. In this communication we will provide input on the appropriateness of the Draft Questions; offer suggestions for other topics that should be addressed by the Authority; and provide some additional references which we feel have significantly contributed to the global understanding of the treatment of obesity as a disease - and the attendant co-morbid conditions associated with obesity. Moreover, we would welcome any opportunity to actively work with you toward developing meaningful approaches to the care of a disease which affects 2/3 of our state's population.

Upon review of the Draft Key Questions, there are some points which should be clarified.

Question 1: What is the comparative clinical evidence for bariatric surgical procedures versus conventional weight-loss management in:

a. Adults (i.e., age 21 years and older)?
b. Children (age <21), on an overall basis and by specific age groups (i.e., 18 – 21, 13-17, 12 or less)?

At the present time, there are no programs in Washington that are performing bariatric surgery on children. Unfortunately, children and adolescents are significantly affected by the obesity epidemic. While we recognize that this is a major health problem; it will have to be addressed within the context of a program that can address all of the needs of the patient as well as the home environment from which the child comes. To this end, the University of Washington and Seattle Children's Hospital are exploring collaborative mechanisms to construct such a program. In the interim, we feel that there may be unique circumstances where bariatric surgical intervention would be of merit; these should be handled on an individual, case-by-case basis.

As to the definition of "adult" being age 21 and older; most experts consider patients candidates for bariatric surgery when they are 18 years of age and older. In selected individual circumstances, younger patients may be considered if there is radiographic evidence that growth plates have closed; and psychosocial evaluation reveals they are

capable of dealing with the post bariatric surgery lifestyle changes necessary for long-term success.

Question 2: What components of the management of patients undergoing bariatric surgery (e.g., selection of candidates for surgery, multi-disciplinary care team, pre- and/or post-procedure counseling and support) appear to be correlated with higher levels of "treatment success" (e.g., sustained weight loss, reduction in comorbidity burden, etc.)?

In 2014, there is no surgeon or surgical practice in Washington that is not affiliated with a Bariatric Center of Excellence (COE). It can be debated as to whether outcomes are better in a COE versus a non-COE program. What is indisputable however, are the requirements for becoming a COE. These are rigorous certification processes requiring that all elements of a comprehensive, multi-disciplinary program are met. Therefore, all of the programs in our state use the NIH Guidelines for patient selection; all involve a multidisciplinary care team; all involve pre and post –procedure counseling and support; all programs make every effort to follow their patients long-term.

Question 3: What are the short- and long-term harms of bariatric surgery procedures, including rates of procedure-specific and general surgical complications, longer-term morbidity, mortality, and requirements for procedure revision/and or reversal?

There is a prevalent misconception that bariatric surgery is associated with more complications than other surgical procedures. Table 1 summarizes data gathered from Medicare and Medicaid inpatient discharges for patients undergoing the indicated procedures. It is clear from this data that bariatric surgery is no riskier than, and any of the listed surgical procedures, and safer than most.

Procedure		Complications	Mortality
Bariatric surgeries	Gastric bypass	0.4%	0.2%
	Gastric banding	*	*
Other common procedures	Colectomy	2.4%	0.8%
	Hysterectomy	0.4%	*
	Cholecystectomy	0.9%	0.9%
	Hip replacement	1.0%	0.2%

Table 1: CMS comparison of complication and mortality rates among commonly performed surgical procedures in US hospitals. Direct Research LLC, Center for Medicare and Medicaid Services. FY 2010 MedPAR. Medicare Fee-for –Service Inpatient Discharges with Selected Procedures

The Bariatric Outcomes Longitudinal Data Base (BOLD) is a registry of self- reported bariatric surgery patient information from the ASMBS – Bariatric Surgery Center of Excellence participants. A total of 57,918 patients comprised the study population. Table 2 details the procedure specific complication

Complications/adverse events

Variable	All procedures	RYGB	AGB	Sleeve	BPD/DS
Total					
Procedures	57,918	30,864	22,715	1,328	499
Complications	9,967	7,494	1,433	235	256
Patients with ≥1 complication	6,240 (10.77)	4,588 (14.87)	1,050 (4.62)	144 (10.84)	128 (25.65)
Intraoperative complications					
Complications (n)	634	448	92	18	24
Patients (n)	550	385	88	16	17
Predischarge complications					
Complications (n)	2,687	2,078	326	74	63
Patients (n)	2,097	1,613	283	52	43
Postdischarge complications					
Complications (n)	6,646	4,968	1,015	143	169
Patients (n)	4,170	3,060	724	87	90

Abbreviations as in Table 5.
Data in parentheses are percentages.
Overall, 9,967 complications were reported in 6,240 patients during the following periods: intraoperatively, postoperatively but before discharge, and within 1 year of discharge (some patients experienced complications in >1 period).
Conversion from laparoscopic to open surgical access was not included as a complication.

A comparison of this data reveals that the rate of complication increases in proportion to the complexity of the operation. Adjustable gastric banding is the least complicated surgical procedure, followed by sleeve gastrectomy, RYGB and BPD/DS with complication rates of: 4.6%; 10.8%; 14.87%; and 25.65% respectively. It should be noted that these rates are inversely proportional to the weight loss with each procedure (DeMaria et al., 2010).

Question 4: What is the differential effectiveness and safety of bariatric surgery procedures according to health-system and/or program factors such as:

a. Surgeon experience
b. Procedure volume
c. Type of Procedure
d. Laparoscopic vs. open approach: Bariatric surgery has become one of the most commonly performed general surgery procedures and it is almost exclusively performed laparoscopically with a good safety profile (Finks JF, Dimick JB An updated National Institutes of Health Consensus Panel on Bariatric Surgery. JAMA Surgery Published online October 1, 2014). It is very rare for any bariatric procedure performed in this day and age to be done so as an open procedure primarily. The open approach is generally reserved if difficulties are encountered preventing the progression of a laparoscopic operation. Conversion to an open approach occurred in onlt 274 of 57,918 bariatric surgical procedures in the BOLD database (De Maria EJ et al. Baseline data from the American Society for Metabolic and Bariatric Surgery-designated Bariatric Surgery Centers of Excellence using the Bariatric Outcomes Longitudinal Database. SOARD 6 (2010) 347-355).
e. Certification of surgery center
f. Members of core team
g. Type of pre-procedure preparation/post-procedure support
h.

Aside from the comment for 4 d., there is ample data in the literature to address each of the other points.

Question 5: What is the differential effectiveness and safety of bariatric surgery procedures according to patient and/or clinical factors such as:

a. Age (both chronological and physiologic/skeletal)
b. Gender
c. Race/ethnicity
d. BMI (assessed as both continuous and categorical variable)
e. Presence of comorbidities (e.g., hypertension, Type 2 diabetes)
f. Prior event history (e.g., myocardial infarction, stroke)
g. Smoking status
h. Psychosocial health

There is ample data in the literature to address these items.

Question 6: What are the costs and cost-effectiveness of the major bariatric surgery procedures of focus in this evidence review?

With regard to cost effectiveness of bariatric surgery in general, there is data to support both positions that bariatric surgery is cost effective; and that it is not. What is emerging to be a more clear cost benefit analysis is the effect of bariatric surgery on type 2 diabetes over all weight classes from Class I through Class III Obesity.

> Bariatric surgery appears to be a clinically effective and cost-effective intervention for moderately to severely obese people compared with non-surgical interventions. Uncertainties remain and further research is required to provide detailed data on patient QoL; impact of surgeon experience on outcome; late complications leading to reoperation; duration of comorbidity remission; resource use. Good-quality RCTs will provide evidence on bariatric surgery for young people and for adults with class I or class II obesity. New research must report on the resolution and/or development of comorbidities such as Type 2 diabetes and hypertension so that the potential benefits of early intervention can be assessed (Picot et al., 2009).
>
> Bariatric surgery is to date the most effective treatment for morbid obesity and it has been proven to reduce obesity-related comorbidities and total mortality. As any medical treatment, bariatric surgery is costly and doubts about its affordability have been raised. On the other hand, bariatric surgery may reduce the direct and indirect costs of obesity and related comorbidities. The appreciation of the final balance between financial investments and savings is critical from a health economic perspective. The epidemic of obesity may cause a significant reduction in life expectancy and overwhelming direct and indirect costs for citizens and societies. Cost-efficacy analyses included in this review consistently demonstrated that the additional years of lives gained through bariatric surgery may be obtained at a reasonable and affordable cost. In groups of patients with very high obesity-related health costs, like patients with type 2 diabetes, the use of bariatric surgery required an initial economic investment, but may save money in a relatively short period of time (Terranova et al., 2012).
>
> To analyze the cost-effectiveness of bariatric surgery in severely obese (BMI 35 kg/m2) adults who have diabetes, using a validated diabetes cost-effectiveness model. The costs and quality adjusted life-years (QALY), and cost-effectiveness of gastric bypass surgery relative to usual diabetes care and of gastric banding surgery relative to usual diabetes care were separately analyzed. The cost-effectiveness of each type of surgery for severely obese individuals who are newly diagnosed with diabetes and for severely

> obese individuals with established diabetes were analyzed. In all analyses, bariatric surgery increased QALYs and increased costs. Bypass surgery had cost-effectiveness ratios of $7,000/QALY and $12,000/QALY for severely obese patients with newly diagnosed and established diabetes, respectively. Banding surgery had cost-effectiveness ratios of $11,000/QALY and $13,000/QALY for the respective groups. These cost-effective ratios are lower than the cost effectiveness ratios for commonly applied diabetes interventions and well below the $50,000/QALY benchmark sometimes applied as a measure of society's willingness to pay for health interventions in sensitivity analyses, the cost-effectiveness ratios were most affected by assumptions about the direct gain in QoL from BMI loss following surgery. This analysis indicates that gastric bypass and gastric banding are cost effective methods of reducing mortality and diabetes complications in severely obese adults with diabetes (Hoerger et al, 2010).

For the super obese, people with a body mass index (BMI) of 50 or greater (for example, a person who weighs 350 pounds and stands 5 feet 10 inches tall), the cost per quality-adjusted life year is actually negative. This means that, over a lifetime, the cost of bariatric surgery is less than the health-care costs associated with not having the procedure. For the severely obese, people with BMIs of 40-50, the cost per QALY is about $1,900 for those with obesity-related disease and about $3,800 for those who are otherwise healthy. And for the moderately obese, people with BMIs of 35-40, the cost per QALY is about $2,400 for those with related medical problems and $3,900 for those who are healthy. While costs increase for healthier, less obese patients, all amounts are well below the $50,000 threshold. Other similar studies have found higher costs associated with bariatric surgery because they did not take the lifetime medical costs of the obesity-related diseases into consideration (Chang et al., 2011).

Demonstration of the clinical needs and the clinical effectiveness of bariatric surgery cannot be the sole determinant for advocacy of bariatric surgery for Class I obesity. An evaluation of the economic effects is also needed. Cost-benefit analyses of obesity and of bariatric surgery are now becoming available (Picot et al., 2009; Cremieux et al., 2008) and the economic value of more active intervention is being debated (Buchanan, 2010; Salem et al., 2005; Finkelstein, 2008).

A recent systematic review and economic evaluation of bariatric surgery for different BMI groups found that bariatric surgery was a clinically effective and cost-effective intervention for moderately to severely obese people compared with non-surgical interventions. Specifically, this analysis showed that bariatric surgery for patients with BMI 30-35 produced incremental cost-effectiveness ratios that were within the cost-effective range (Picot et al., 2009).

Review of Current Uniform Medical Plan

Finally, we feel that current policies for Bariatric Surgery should be reviewed and modified. State employees receiving coverage under the Uniform Plan are assigned a case manager who works with the patient for 6 month prior to an evaluation by a bariatric surgeon.

Current Uniform Medical Plan Exerpt

Once your application for bariatric surgery is accepted, you will be assigned a Regence case manager. Before referral to a bariatric Center of Excellence, the following criteria must be met:

1. Participation in a structured, medically supervised weight-loss program* for at least six months. Clinical records must be provided that demonstrate that the program:

- Includes at least three visits for medical supervision occurring no more than four months apart (for example, at the start, midpoint, and end of a six-month program) These visits must include assessment and evaluation of weight loss, diet, exercise, and behavior modification.
- Is supervised by an MD, DO, ARNP, or PA; or by a registered dietician under the supervision of an MD, DO, ARNP, or PA.

**A comprehensive commercial program (such as Weight Watchers) may be acceptable, but must still fulfill the criteria listed above. Your Regence Case Manager will work with you to ensure the program you choose fulfills the necessary criteria. You are responsible for all costs associated with such a weight-loss program.*

2. Psychological evaluation by a licensed psychiatrist, psychologist, or licensed clinical social worker. This evaluation must document the absence of significant psychological issues that could limit the member's ability to comply with medical/surgical recommendations.

3. Clinical documentation that the member is willing and able to comply with preoperative and postoperative treatment plans

There are some major issues of concern with the current policy. The first is that patients are put on a course for possible weight loss surgery prior to it being determined that they are in fact, a candidate for surgery. This is an assessment that can only be performed by a surgeon after fully evaluating the patient. There have been patients that have completed the 6 month preparatory program, only to find that they are not bariatric surgical candidates because of some prior procedure or medical condition that would preclude bariatric surgery. This is wasting the time and resources that were used to prepare a patient for a procedure that, once fully evaluated, they are not a candidate for. The patient should be evaluated prior to undertaking the preparatory program.

Second, the individual charged with this "medically supervised weight-loss program* for at least six months" in all likelihood lacks the necessary training to orchestrate such a program. If this requirement is to be upheld, it should be done so by a practioner with the skill and training to effectively execute a medically supervised weight loss program. The last 30 years of the American health care experience would suggest that this is beyond the scope of most primary care providers.

Finally the requirement for such a program has fallen under recent critical review by the ASMBS. The following is from a recent ASMBS Position Statement on Preoperative Supervised Weight Loss Requirements.

> Many health insurance carriers, including those who administer the Medicare program, require 6–12 months of recent documentation of diet attempts before authorization is granted to provide coverage for bariatric surgery services. This is mandated in the absence of any regard for the individual patient's history of past efforts and often without any expectation of successful weight loss.
>
> Such policies typically ignore the patient's health circumstances related to morbid obesity and the status of potentially life-threatening co-morbid conditions. Most policies require rigorously documented physician encounters, including monthly chart entries conforming to a specific format.
>
> Carriers often penalize patients who miss a single monthly visit by forcing them to reinitiate the entire process. This process can be financially onerous, frustrating, and time-consuming for many patients. Medicare and many other payors do not pay for dietary treatment, and patients

must take time off from work or family responsibilities to visit their physician. Programs, such as Weight Watchers and Slim-Fast, typically do not meet the insurance carriers' requirements. To date, no class I studies or evidence-based reports has documented the benefits of, or the need for, a 6 –12-month preoperative dietary weight loss program before bariatric surgery. The current evidence supporting preoperative weight loss involves physician-mandated weight loss to improve surgical risk or to evaluate patient adherence. Although many believe benefits could result from acute preoperative weight loss in the weeks before bariatric surgery, the available class II–IV data regarding acute weight loss before bariatric surgery are indeterminate and provide conflicting results, leading to no clear consensus at this time. The preoperative weight loss recommended by the surgeon and/or the multidisciplinary bariatric treatment team because of an individual patient's needs might have value for the purposes of improving surgical risk or evaluating patient adherence. However, it is supported only by low-level evidence in the published data at present.

One effect of mandated preoperative weight management before bariatric surgery is the attrition of patients from bariatric surgery programs. This barrier to care is likely related to patient inconvenience, frustration, healthcare costs, and the lost income resulting from the requirement for repeated physician visits not covered by health insurance. It is the position of the American Society for Metabolic and Bariatric Surgery that the requirement for documentation of prolonged preoperative diet efforts before health insurance carrier approval of bariatric surgery services is inappropriate, capricious, and counterproductive, given the complete absence of a reasonable level of medical evidence to support this practice. Policies such as these that delay, impede, or otherwise interfere with life-saving and cost-effective treatment, which has been proved to be true for bariatric surgery to treat morbid obesity, are unacceptable without supporting evidence. Individual surgeons and programs should be free to recommend preoperative weight loss according to the specific needs and circumstances of the patient (ASMBS Position Statement on Preoperative Supervised Weight Loss Requirements, 2011)

Conclusion

We are grateful for the opportunity to offer commentary on the Draft Questions put forth by the Washington State Health Care Authority. We would like to offer our collective expertise to assist in any way, as the Authority reviews its coverage policy for bariatric surgery. The WA ASMBS is willing to assist the Authority in any way we can to provide the care to those in our state suffering from obesity and its related co-morbidities.

Citations

ASMBS Position Statement on Preoperative Supervised Weight
Loss Requirements. Surgery for Obesity and Related Diseases 7 (2011) 257–260.

Buchanan TA. Stemming the tide of type 2 diabetes: bring on the "big guns". Obesity 2010; 18(6):1065-7.

Cremieux PY, Buchwald H, Shikora SA, et al. A study on the economic impact of bariatric surgery. Am J Manag Care 2008; 14(9):589-96.

DeMaria EJ, Pate V, Warthen M et al., Baseline data from American Society for Metabolic and Bariatric Surgery-designated Centers of Excellence using the Bariatric Outcomes Longitudinal Database. SOARD 2010: (6); 347-55.

DeMaria EJ, Pate V, Warthen M et al. Mortality rate when performed at a Bariatric Surgery Center of Excellence; Bariatric Surgery: Baseline data from American Society for Metabolic and Bariatric Surgery-designated Bariatric Surgery Centers of Excellence using the Bariatric Outcomes Longitudinal Database, Surgery for Obesity and Related Diseases. Article in Press.

Dolan JP, Diggs BS, Sheppard BC et al. The National Mortality Burden and Significant Factors Associated with Open and Laparoscopic Cholecystectomy: 1997–2006. J Gastrointest Surg. 2009; 13:2292-2301
Himpens J, Dobbeleir J, Peeters G. Long-term Results of Laparoscopic Sleeve Gastrectomy for Obesity. Annals of Surgery • Volume 252, Number 2, August 2010

Hoerger TJ, Zjang P, Segel JE, Kahn HS, Barker LE, Couper S. Cost-effectivenss of bariatric surgery for severely obese adults with diabetes. *Diabetes Care* 33:1933–1939, 2010

Lie SA, Engesaeter LB, Havelin LI et al. Early postoperative mortality after 67,548 total hip replacements. Acta Orthopaedica 2002; 73(4):392-399

Picot J[1], Jones J, Colquitt JL, Gospodarevskaya E, Loveman E, Baxter L, Clegg AJ. The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. Health Technol Assess. 2009 Sep;13(41):1-190, 215-357

Puzziferri N, Roshek TB, Mayo HG, Gallagher R, Belle SH, Livingston EH. Long-term Follow-up After Bariatric SurgeryA Systematic Review. JAMA. 2014;312(9):934-942

Ricciardi R; Virnig BA, Ogilvie Jr. JW. Volume-Outcome Relationship for Coronary Artery Bypass Grafting in an Era of Decreasing Volume. Arch Surg. 2008;143[4]:338-344

Salem L, Jensen CC, Flum DR. Are bariatric surgical outcomes worth their cost? A systematic review. J Am Coll Surg 2005; 200(2):270-8.

Su-Hsin Chang, Carolyn R.T. Stoll, Graham A. Colditz. Cost-effectiveness of bariatric surgery: Should it be universally available? *Maturitas*, 2011; 69 (3): 230 DOI: 10.1016/j.maturitas.2011.04.007

Terranova L[1], Busetto L, Vestri A, Zappa MA. Bariatric surgery: cost-effectiveness and budget impact. Obes Surg. 2012 Apr;22(4):646-53.

Recommended References

The WA-ASMBS feel that the following reference documents represent the state of the art of bariatric surgery, and should be reviewed and used to guide the implementation of any health care policy.

ASMBS Position Statement on Preoperative Supervised Weight Loss Requirements. Surgery for Obesity and Related Diseases 7 (2011) 257–260

ASMBS Position Statement on Class I Obesity (BMI 30-35kg/). Available at www.ASMBS.org

ASMBS Position Statement on Sleeve Gastrectomy as a Bariatric Prcedure. Revised 10/28/2011. Available at www.ASMBS.org

Colquitt JL, et al. Surgery for weight loss in adults. *The Cochrane database of systematic reviews*. 2014;8:Cd003641

Carlin AM et al. The Comparative Effectiveness of Sleeve Gastrectomy, Gastric Bypass, and Adjustable Gastric Banding Procedures for the Treatment of Morbid Obesity. Carlin AM et al. 2013 Anals of Surgery 257:5; 791-797

Mingrone G, Panunzi S, De Getano A, et al. Bariatric surgery versus conventional medical therapy for type 2 diabetes. N Engl J Med 2012;366:1577-85.

Leonetti F, Capoccia F, Cassella G et al. Obesity, tyoe 2 diabete mellitus, and other comorbidities. Arch Surg 2012 Aug, 147 (8):694-700.

Schauer PR, Kashyap SR, Wolski K et al. Bariatric Surgery versus intensive medical therapy in obese patients with diabetes. N Engl J Med 2012;366:366:1567-76.

Schauer PR, Bhatt DL, Kirwan JP et al. Bariatric surgery versus intensive medical therapy for diabetes – 3 year outcomes. N Engl J Med. March 31, 2014 at NEJM.org DOI: 10.1056/NEJMoal401329.