

March 29, 2016

Jacquelyn Walsh
V.P. for Clinical Excellence and Quality
Blue Cross/Blue Shield – North Dakota
4510 13th Ave. S.
Fargo, ND 58121

Dear Ms. Walsh:

This letter is to request that BCBS-ND revisit its bariatric surgery policy in the area of Type 2 Diabetes Mellitus (T₂DM).

As you are likely aware, the Park Rapids Bariatric Surgery Program provides bariatric surgical services for all of Essentia-West, which includes all of its North Dakota locations. We presently are the only provider that is a BCBS Blue Distinction Center for Bariatric Surgery (enabling us to treat BCBS patients) in Minnesota north of the Twin Cities. It is from that vantage point, as Medical Director of the Park Rapids Bariatric Surgery Program, as well as the American Society for Metabolic and Bariatric Surgery (ASMBS) of which I am a member of its Access to Care Committee, that we request this review.

During February 2015 we sent some public comments regarding the changes proposed in the BCBS-ND policy on bariatric surgery. On review of the finalized policy (effective 11/17/15) we were pleased by the change lifting the “one bariatric surgery per lifetime” restriction. This was putting many patients in a very bad position (e.g., patients who have developed an intolerance to their adjustable gastric band). Lifting that restriction allows those patients to receive adequate/standard care.

Our remaining area of concern has to do with the restriction of bariatric surgery in the current BCBS-ND policy for patients with T₂DM with BMIs 35.0-39.9 to only those patients with: “uncontrolled Type 2 Diabetes indicated by an A₁C>7 (Diabetes Care. Vol. 28; Sup. 1 “American Diabetes Assn Clinical Practice Guidelines: 2005. PS10”) (page 3 in the current BCBS-ND policy). This forces patients to wait for surgery until medical management becomes ineffective, i.e., late in the natural history of T₂DM.

This memo will reiterate some of the points made on our previous public comment regarding the Proposed Bariatric Surgery Coverage Policy (2/4/15) and add some additional information pointing out that surgical treatment is best provided early in the course of T₂DM, rather than late,

as in the case of patients with HgA1C levels >7. Included is a full reference list, as well as partial or full copies of the most pertinent references.

Medical management of T₂DM, while improving, is still associated with, over time, a relentless need to increase the intensity of medical management. Most diabetic medications, especially insulin, cause a gain in weight, resulting in a vicious cycle of more insulin resistance, requiring progressively higher doses of medications. Even with escalation in intensity of medical management, T₂DM results in deaths due to cardiovascular disease in 60-70% of patients, and remains the leading cause of adult blindness, amputation, and end-stage renal disease. On the other hand, surgery, especially if done early in the disease, offers an opportunity for sustained remission or at least a better control of T₂DM over time. Surgery has been shown to reduce mortality related to diabetic complications, compared to a non-surgical treatment. Adams et al.,¹ reports on a United States study with 7925 patients in the surgical group (Roux-en-Y gastric bypass) and a non-surgical matched control group followed for a mean of 7.1 years. In that study, the adjusted long-term mortality from any cause in the Roux-en-Y gastric bypass group decreased by 40%, as compared to that of the control group. Cause-specific mortality in the Roux-en-Y gastric bypass group decreased by 56% for coronary artery disease, by 60% for cancer, and by 92% for diabetes.

T₂DM is associated with an ongoing, progressive loss of pancreatic beta cell mass, which, along with progressively increasing insulin resistance over time, are reasons that the medical management needs to be progressively increased in T₂DM patients. Because of several possible mechanisms, bariatric surgery stops or slows pancreatic beta cell loss. Bariatric surgery is also shown to decrease insulin resistance. Together these result in markedly better outcomes in surgical treatment of diabetes. The Swedish Obese Study² demonstrates this well. See Figure 1 below.

Figure 1: Swedish Obese Study²

		Surgical	Matched Control
Prevention	2 year incident	1%	8%
	10 year incident	8%	24%
Remission	2 year remission	72%	21%
	10 year remission	36%	13%

Sjostrom et al.²

In addition to having many T₂DM patients go into remission, the SOS study showed bariatric surgeries to be useful also in prevention of T₂DM. In the surgical studies, “remission” is generally defined as a normal hemoglobin A₁C and off all diabetic medications. When looking at the SOS outcomes over a ten-year period, more than one-third of the surgical patients remain in remission, avoiding the medical complications, higher risk of death, and expense of T₂DM.

The Policy would limit bariatric surgery to patients with T₂DM to only those having a hemoglobin A₁C of greater than 7. The citation in the Policy supporting this is the American Diabetes Association Clinical Practice Recommendations: 2005.

The ADA updates these recommendations yearly, and restriction of surgery to only those with hemoglobin A₁Cs of greater than 7 has been absent for several years. This 2005 citation is clearly obsolete. Recommendations similar to the present ADA guidelines were first presented in 2009³ (copy enclosed).

The restrictions of surgery to patients with hemoglobin A₁Cs greater than 7 will tend to delay surgical treatment until medical management becomes ineffective. It is well documented that surgical treatment early in the course of T₂DM is much more likely to result in remission. The findings of the Hayes et al. study⁴ in 2011 highlight this fact.

Figure 2: Resolution of T2 DM at 1 Year⁴

T2 DM Pre-Op Status	1 Year Resolution
Previously Unrecognized	24/24 (100%)
Diet Controlled	11/11 (100%)
Oral Agents Only	56/60 (93%)
On Insulin*	16/32 (50%)

* All these patients improved but 6/32 still on insulin

Hayes et al.⁴

This study looked at the remission rates following gastric bypass in T₂DM patients based on their pre-operative stage of disease. Patients initially diagnosed with T₂DM at the time of pre-operative examination, or were diet controlled, had a one-year resolution of 100%. Those on oral agents alone had a 93% resolution rate, while those on insulin had only a 50% resolution rate.

Keep in mind that the SOS study (and others) show the remission of T₂DM following surgery is maintained in many patients for ten years or longer. To withhold surgical treatment in the early stages of diabetes at a point that surgery results in a high rate of remission, thereby avoiding the complications of T₂DM and its associated increase in mortality, can only be recognized as both bad medicine and highly unethical.

Hayes⁴ concluding paragraph is as follows:

“Resolution of T₂DM and the knowledge of reduced disease-specific mortality in this group of severely obese patients, coupled with knowledge of the ongoing morbidity and risks faced by severely obese diabetics makes bariatric surgery an important option which needs to be discussed with all such patients. Some indication of the expected prospect of resolution of diabetes should be part of that discussion. The finding that the strongest independent negative predictors of resolution are a requirement for insulin therapy and a high HbA₁C, **makes it desirable that such a discussion take place even in otherwise reasonably controlled diabetics, before the disease progresses to poor control.**”

National and international standards of care regarding access to bariatric surgery

In March 2011, the International Diabetes Federation published a position statement titled “Bariatric Surgical & Procedural Interventions in the Treatment of Obese Patients with T₂DM.”⁵ With regard to bariatric surgery, this statement regarding standards of care include the following: “Medical therapy and lifestyle changes have very limited success in controlling blood glucose

levels among the severely obese...a number of medications used to treat T₂DM; including insulin, themselves cause weight gain.”

The IDF position statement continues, stating that surgical intervention results in:

- a. “Normalization or improvement of the metabolic state (decreased weight, improved HgbA₁C lipid profiles, and hypertension).”
- b. “Generates both cost savings and health benefits over the patient’s lifetime.”
- c. “Appears to reduce both microvascular and cardiovascular risk.”
- d. “Appears to prevent or slow the progressive loss of beta cell function characteristic of T₂DM.”

We agree that the American Diabetic Association standards of care are an important reference, but it is obvious that current standards, as opposed to the 2005 standards, be used. Enclosed is the section on treatment of obesity in the 2016 ADA Standards.⁶

The 2016 ADA Standards has a “boxed” recommendation: “Bariatric surgery should be considered for adults with BMI ≥ 35 kg/m² and T₂DM, especially if the diabetes is difficult to control with lifestyle and pharmacologic therapy.” Note that there are no specific restrictions beyond having a BMI of at least 35.

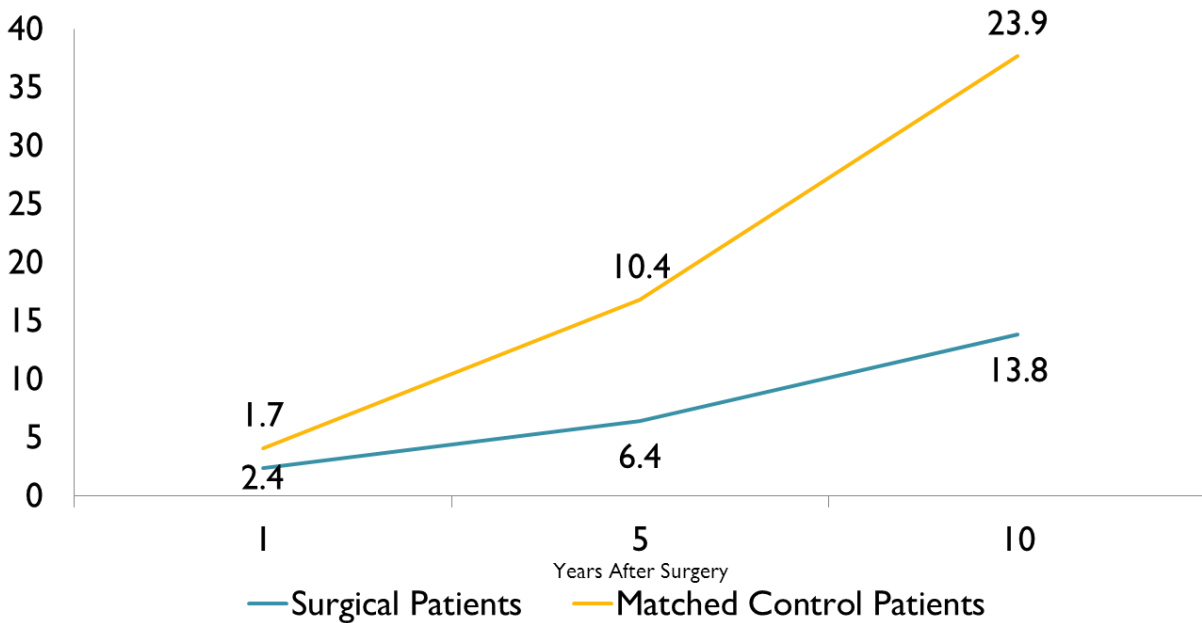
Additional statements for the 2016 ADA standards regarding bariatric surgery include:

- a. “National guidelines support consideration of bariatric surgery for people with type 2 diabetes with BMI > 35 kg/m².”
- b. “Treatment with bariatric surgery has been shown to achieve near or complete normalization of glycemia 2 years following surgery in 72% of patients, compared with 16% in a matched control group treated with lifestyle and pharmacological interventions.”
- c. **“Younger age, shorter duration of type 2 diabetes, lower A₁C, higher serum insulin levels, and nonuse of insulin have all been associated with higher remission rates after bariatric surgery.”**

Of note, under the section “Disadvantages,” a 2010 VA study showed no mortality benefit of surgery compared to non-surgical/usual care. This finding was refuted in a much larger VA study recently published.

A study comparing outcomes of surgical versus non-surgical treatment of morbid obesity was published in January 2015 in the Journal of the American Medical Association.⁷ This compared the death rates of all patients nationwide having bariatric surgery at VA hospitals to a control group matched for age, BMI, sex, and co-existing diseases and conditions (Figure 3).

Figure 3: Nationwide VA Hospital Study: Bariatric Surgery Cuts Death Rate Nearly in Half vs. Matched Controls⁷



Arteburn et al.⁷

This study shows that the death rate was close to half in the surgical group versus the non-surgical group. This VA study is felt to be important in that most previous bariatric surgery outcome studies had a large number of younger females, while this study had a predominance of older, generally sicker, males.

It is clear using current standards, surgical treatment of T₂DM with patient BMIs of 35-40 should not be restricted by requirements such as hemoglobin A₁C greater than 7, but should be offered as an option early in the course of the disease in patients otherwise deemed appropriate surgical candidates.

Approaching these patients from a different angle, one could ask, “What are the standards of care for treatment of obesity per se with regard to T₂DM”.

The Obesity Society, American College of Cardiology, and the American Heart Association, in collaboration with the National Heart, Lung, and Blood Institute (NHLBI – a division of the NIH; i.e., this is the current NIH guideline), brought together an expert panel to develop guidelines for the treatment of obesity.⁸ Of note, the panel had 19 experts, only one of whom was a surgeon.

Figure 4: Guidelines (2013) For Managing Overweight and Obesity in Adults⁸

GUIDELINES (2013) FOR MANAGING OVERWEIGHT AND OBESITY IN ADULTS

Full Report including the Executive Summary – published by The Obesity Society with the ACC/AHA Task Force on Practice Guidelines and based on a Systematic Evidence Review supported by the NHLBI

Endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Pharmacists Association, American Society for Nutrition, American Society for Parenteral and Enteral Nutrition, American Society for Preventive Cardiology, American Society of Hypertension, Association of Black Cardiologists, National Lipid Association, Preventive Cardiovascular Nurses Association, The Endocrine Society, and WomenHeart: The National Coalition for Women With Heart Disease

Figure 5 presents the guidelines produced by this panel. In reviewing this, it is important to re-emphasize that these represent the current standards of care for the treatment of obesity by the National Institutes of Health. The guideline labeled Box 13 clearly states “BMI >40 or BMI >35 with comorbidities. Offer referral to an experienced bariatric surgeon for consultation and evaluation as an adjunct to lifestyle intervention.” As T₂DM is one of the comorbidities indicated for surgical treatment of obesity in patients with BMI >35, this algorithm is clear - a health policy not covering bariatric surgery for patients with T₂DM with BMIs between 35.0 and 39.9 is inconsistent with the standards of care of the National Institutes of Health. It is notable that the recommendation is listed as having a grade “A”, the highest possible grade (Figure 6).

Figure 5: Treatment Algorithm – Chronic Disease Management Model for Primary Care of Patients with Overweight and Obesity⁸

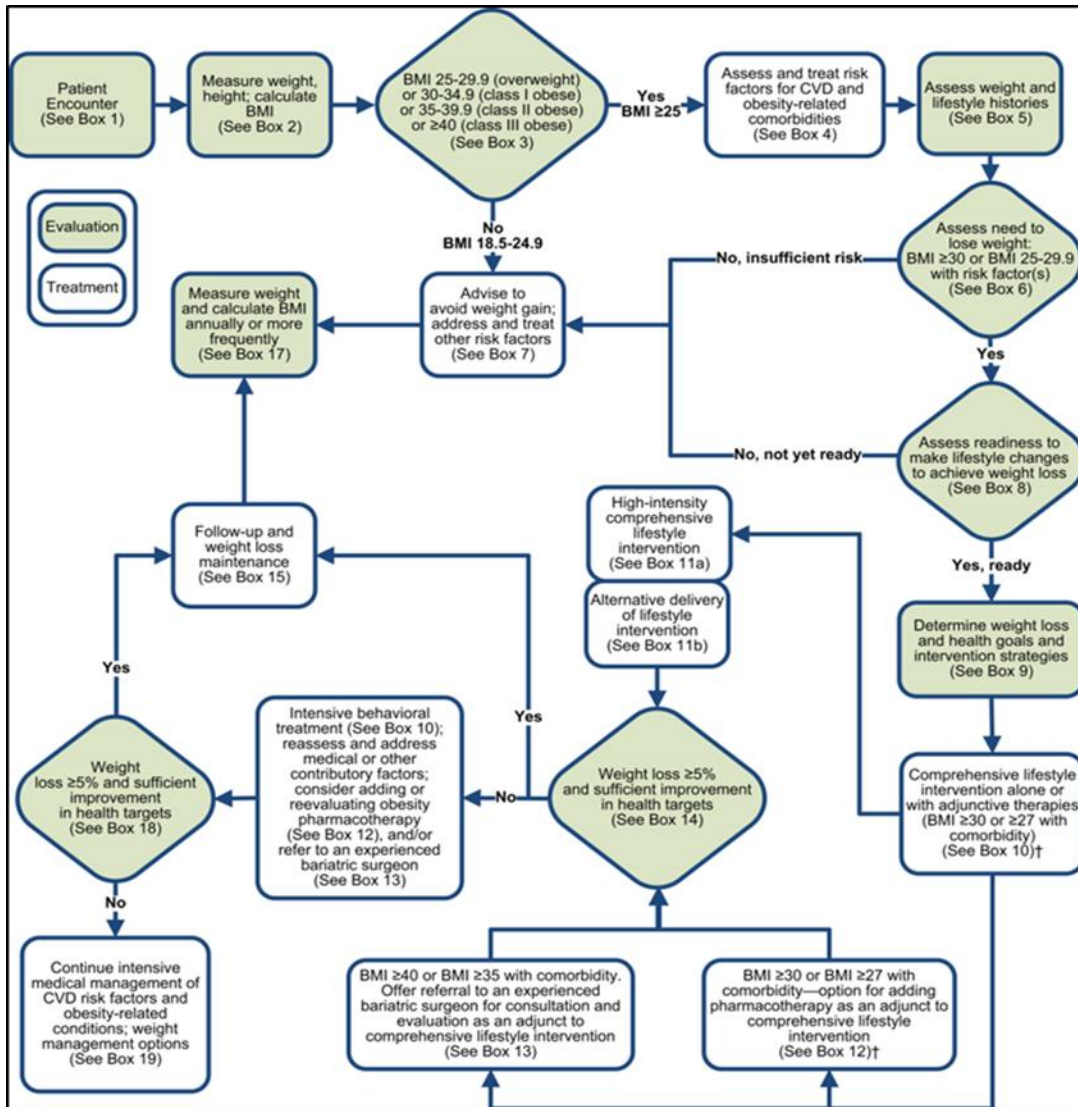


Figure 6: Summary of Recommendations for Obesity⁹

TABLE 4 Summary of Recommendations for Obesity (Continued)

Recommendations	NHLBI Grade	NHLBI ES	ACC/AHA COR	ACC/AHA LOE
Lifestyle Intervention and Counseling (Comprehensive Lifestyle Intervention)				
4a. Advise overweight and obese individuals who would benefit from weight loss to participate for ≥ 6 months in a comprehensive lifestyle program that assists participants in adhering to a lower-calorie diet and in increasing physical activity through the use of behavioral strategies.	A (Strong)	CQ4	I	A
4b. Prescribe on-site, high-intensity (i.e., ≥ 14 sessions in 6 mo) comprehensive weight loss interventions provided in individual or group sessions by a trained interventionist.	A (Strong)	CQ4	I	A
4c. Electronically delivered weight loss programs (including by telephone) that include personalized feedback from a trained interventionist can be prescribed for weight loss but may result in smaller weight loss than face-to-face interventions.	B (Moderate)	CQ4	Ila	A
4d. Some commercial-based programs that provide a comprehensive lifestyle intervention can be prescribed as an option for weight loss, provided there is peer-reviewed published evidence of their safety and efficacy.	B (Moderate)	CQ4	Ila	A
4e. Use a very-low-calorie diet (defined as < 800 kcal/d) only in limited circumstances and only when provided by trained practitioners in a medical care setting where medical monitoring and high-intensity lifestyle intervention can be provided. Medical supervision is required because of the rapid rate of weight loss and potential for health complications.	A (Strong)	CQ4	Ila	A
4f. Advise overweight and obese individuals who have lost weight to participate long term (≥ 1 year) in a comprehensive weight loss maintenance program.	A (Strong)	CQ4	I	A
4g. For weight loss maintenance, prescribe face-to-face or telephone-delivered weight loss maintenance programs that provide regular contact (monthly or more frequently) with a trained interventionist who helps participants engage in high levels of physical activity (i.e., 200–300 min/wk), monitor body weight regularly (i.e., weekly or more frequently), and consume a reduced-calorie diet (needed to maintain lower body weight).	A (Strong)	CQ4	I	A
Selecting Patients for Bariatric Surgical Treatment for Obesity (Bariatric Surgical Treatment for Obesity)				
5a. Advise adults with a BMI ≥ 40 kg/m ² or BMI ≥ 35 kg/m ² with obesity-related comorbid conditions who are motivated to lose weight and who have not responded to behavioral treatment with or without pharmacotherapy with sufficient weight loss to achieve targeted health outcome goals that bariatric surgery may be an appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation.	A (Strong)	CQ5	Ila	A
5b. For individuals with a BMI < 35 kg/m ² , there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures.	N (No Recommendation)	CQ5	—	—
5c. Advise patients that choice of a specific bariatric surgical procedure may be affected by patient factors, including age, severity of obesity/BMI, obesity-related comorbid conditions, other operative risk factors, risk of short- and long-term complications, behavioral and psychosocial factors, and patient tolerance for risk, as well as provider factors (surgeon and facility).	E (Expert Opinion)	CQ5	Iib	C

The following additional professional society guidelines consistently recommend that bariatric surgery be a treatment option for individuals with a BMI > 40 kg/m² or > 35 kg/m² with significant comorbidities, all of which consider T₂DM as one of these comorbidities.

- The Institute for Clinical Systems Improvement (ICSI) 2013⁹
- Veterans Administration (VA) Management of Overweight and Obesity Working Group (2014)¹⁰
- Australian National Health and Medical Research Council (2013)¹¹
- National Institute for Health and Care Excellence, UK (NICE) 2014¹²
- American Association of Clinical Endocrinologists, Obesity Society, American Society for Metabolic and Bariatric Surgery (2013)¹³
- Canadian Agency for Drugs and Technologies in Health (2014)¹⁴

The most recent guidelines relating to bariatric surgery were published in August 25, 2015, in “Circulation,” and the September 2015 issue of “Diabetes Care.” This was a joint statement by the American Heart Association and the American Diabetes Association statement entitled “Update on Prevention of Cardiovascular Disease in Adults with T₂DM in Light of Recent Evidence.”¹⁶ This likewise includes a recommendation that adults with BMI >40 or >35 with comorbidities be considered for bariatric surgery. Again, in all of these guidelines one of the comorbidities of making a patient with BMI of 35.0-39.9 eligible for bariatric surgery is the presence of T₂DM; no current guideline restricts the access to surgery to patients with Hgb A₁C≥7, and in fact, argue that treatment early in the course of T₂DM is preferable.

At this point there can be no equivocating: a healthcare policy restricting bariatric surgery to T₂DM patients with BMI 35.0-39.9 to only those having Hgb A₁C≥7 is not consistent with current National and International standards of care!

Cost Implications

It is accepted that bariatric surgery results in significant long-term cost savings as pointed out in the 2010 study conducted by Health Partners (Figure 7).

Figure 7: Longitudinal Cost Experience for Gastric Bypass Patients¹⁶

The image is a screenshot of a research article page. At the top, it shows the journal title "Surgery for Obesity and Related Diseases" and the issue information "Volume 6, Issue 3, May-June 2010, Pages 243-248". The Elsevier logo is on the left. Below the journal information, it says "Original article". The article title is "Longitudinal cost experience for gastric bypass patients" by Deborah M. Mullen, Ph.D. and Thomas J. Marr, M.D. from HealthPartners, Bloomington, Minnesota. It includes the dates: "Received 9 February 2009, Revised 6 January 2010, Accepted 12 January 2010, Available online 1 February 2010".

Abstract

Background To assess the effect of gastric bypass surgery on the total cost of medical care for morbidly obese members compared with obese members and a general population.

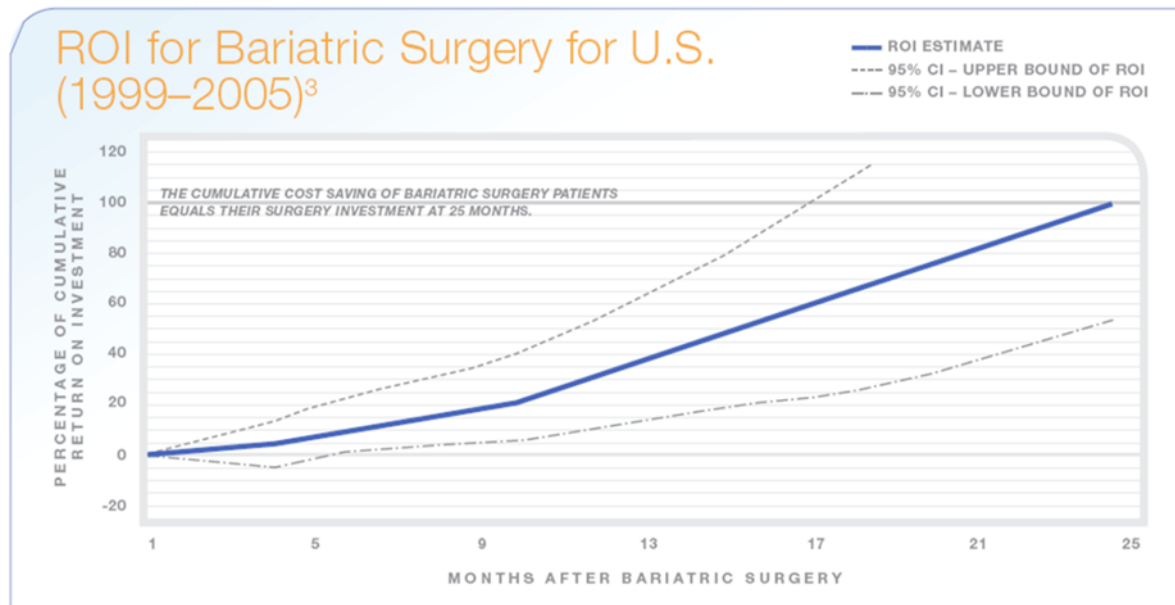
Methods We used an observational pre-post test design to analyze the administrative claim records of 224 gastric bypass patients during 3 periods (preoperative, surgical, and postoperative years) for a total of 7.5 years. The estimated future care costs for gastric bypass patients were determined from their preoperative cost trends, adjusting for the annualized actuarial trends. The general membership population actuarial trends and overweight/obese member medical expenditure data were used as comparison groups.

Results The inflation adjusted mean per member per year total paid decreased by \$1895 in the fifth year after surgery. The mean costs for gastric bypass patients were lower within the first year after surgery than their preoperative costs. At 3.5 years after surgery, the surgical costs had been recouped for patients undergoing gastric bypass surgery, and by year 2, they had incurred fewer costs than the obese health plan population.

Conclusion Although gastric bypass is a costly surgical procedure, the longitudinal costs savings and overall health improvement for patients undergoing gastric bypass surgery are cost-effective within a closed, experienced network. Weight loss surgery decreased the annual costs per patient in the years after surgery. The costs were slightly elevated in the fifth year after surgery because of maternity cases and orthopedic surgeries.

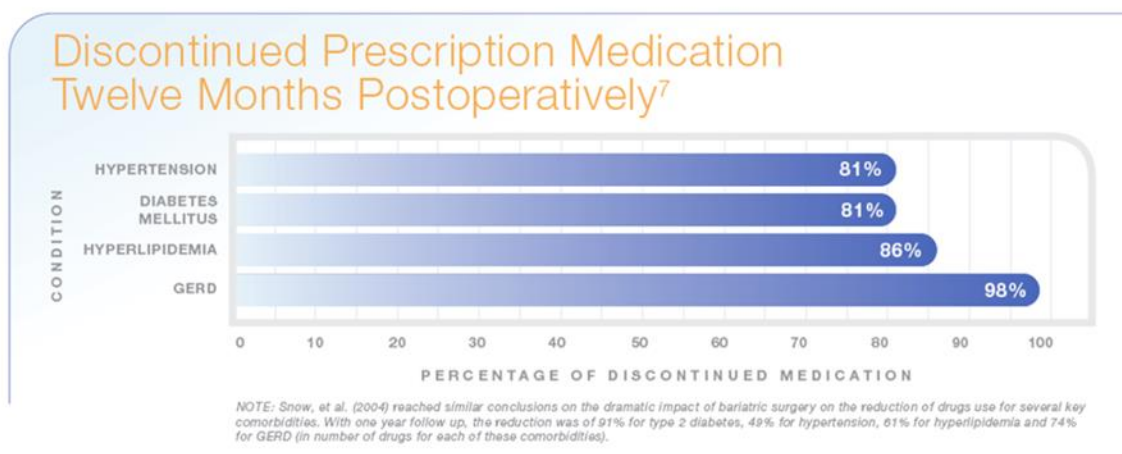
Cremieux et al¹⁸ found that the return on investment for bariatric surgery with the US average is about 24 months (Figure 8).

Figure 8: ROI for Bariatric Surgery for U.S. (1999-2005)¹⁷



Looking at T₂DM specifically, the Nguyen¹⁸ study showed that one year diabetic medication was decreased by 81%.

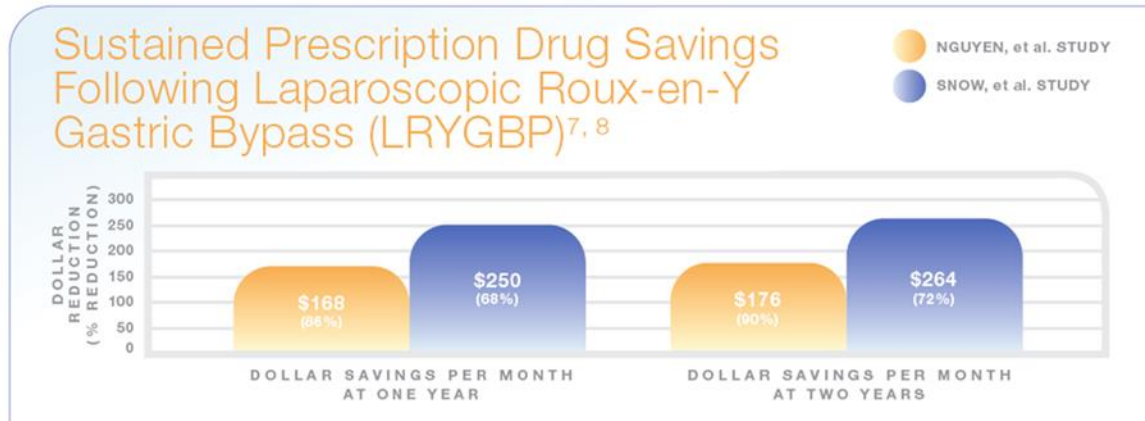
Figure 9: Discontinued Prescription Medication Twelve Months Postoperatively¹⁸



Similar cost savings were reported in the Nguyen and Snow studies (Figure 10).

Figure 10: Effects on Prescription Drug Cost^{18,19}

Effects on Prescription Drug Cost



It is intuitively obvious that treating T₂DM patients earlier rather than later is much more cost effective:

- Early surgical treatment would reduce or avoid the costs of medical management incurred while waiting for the patient to be uncontrolled by non-surgical treatment.
- Earlier surgical treatment, in turn, would decrease the long-term cost of care compared to medical management: higher remission rates = lower costs.

Summary

To personalize this issue, imagine that two patients with new onset T₂DM with BMIs between 35 and 40. One patient was permitted to have surgery early in the course and the other was made to wait until late in the disease, such Hgb A_{1c} ≥ 7 despite medical management. On the one hand, offering the patient treatment early would delay or, in many cases, avoid altogether the ravages of T₂DM (early cardiovascular death, renal failure, amputation, etc.), all the while incurring much less costs of ongoing medical care. On the other hand, waiting until the non-surgical treatment becomes ineffective likely would lead to just the opposite outcome, many more diabetic-related comorbidities and high risk of premature death, and much higher medical costs over time.

In summary, making T₂DM in patients with BMI 35.0-39.9 wait until later in the course of their disease:

- is putting the patient at an unnecessary increased risk of diabetic-related complications and death.
- results in higher costs over time.
- because of a and b above is clearly unethical.
- is inconsistent with all of the current National and International standards of care.

As such, we request that BCBS ND revisit this issue, and we recommend that the requirement be altered such that, consistent with current guidelines: Bariatric surgery be an option for T₂DM patients with BMIs ≥ 35 without restrictions of such requirements as Hgb A₁C ≥ 7 .

I am available anytime to discuss this issue with representatives of BCBS ND. Thank you very much!

Sincerely,

Daniel A.P. Smith, MD

Encl: Copies of key references

References

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