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., 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 Study demonstrates this well. See Figure 1 below.

**Figure 1: Swedish Obese Study**

<table>
<thead>
<tr>
<th></th>
<th>Surgical</th>
<th>Matched Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevention</td>
<td>2 year incident</td>
<td>1%</td>
</tr>
<tr>
<td></td>
<td>10 year incident</td>
<td>8%</td>
</tr>
<tr>
<td>Remission</td>
<td>2 year remission</td>
<td>72%</td>
</tr>
<tr>
<td></td>
<td>10 year remission</td>
<td>36%</td>
</tr>
</tbody>
</table>

Sjostrom et al.

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 2009\(^3\) (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. study\(^4\) in 2011 highlight this fact.

### Figure 2: Resolution of T2 DM at 1 Year\(^4\)

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

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

Hayes\(^4\) 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.

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. 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).
This study shows that the death rate was close to half in the surgical group versus the nonsurgical 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. Of note, the panel had 19 experts, only one of whom was a surgeon.
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 Obesity
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) 2013\(^9\)
- 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) 2014\(^12\)
- 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.” 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 Patients

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Cremieux et al\textsuperscript{18} 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)\textsuperscript{17}**

Looking at T\textsubscript{2}DM specifically, the Nguyen\textsuperscript{18} study showed that one year diabetic medication was decreased by 81%.

**Figure 9: Discontinued Prescription Medication Twelve Months Postoperatively\textsuperscript{18}**

Similar cost savings were reported in the Nguyen and Snow studies (Figure 10).
It is intuitively obvious that treating T2DM patients earlier rather than later is much more cost effective:

a. 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.
b. 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 A1C≥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:

a. is putting the patient at an unnecessary increased risk of diabetic-related complications and death.
b. results in higher costs over time.
c. because of a and b above is clearly unethical.
d. 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

2) Sjostrom et al: Association of Bariatric Surgery with Long-term Remission of Type 2 Diabetes and with Microvascular and Macrovascular complications. JAMA 2014: 311(22): 2297-2304
5) IDF Statement
6) American Diabetes Association. Obesity management for the treatment of Type 2 Diabetes. Sec. 6 in Standards of Medical Care in Diabetes-2016. Diabetes Care 2016. 39 (Suppl. 1): 547-551


