MEMORANDUM

To: Center for Consumer Information and Insurance Oversight
    Centers for Medicare and Medicaid Services
    FFEcomments@cms.hhs.gov

From: Daniel Smith, MD
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Subject: Minnesota 2017 Benchmark Plan Comments

Date: September 25, 2015

On review of the proposed 2017 EHB benchmark plan for Minnesota, it has come to our
attention that bariatric surgery is listed as a “not covered” service.

This memo will outline the following concerns that the bariatric surgery community has
regarding this lack of coverage.

a) Obesity is currently the second leading cause of preventable death in the United
    States, and to deny coverage for the one well established and highly efficacious
    treatment for severe obesity, specifically bariatric surgery, in our view is a serious
    deficiency in coverage.

b) Covering bariatric surgery in the ACA exchange policies is actually quite
    inexpensive, and in a short time pays for itself and over a period of time saves the
    payers substantial money.

c) Not covering bariatric surgery is contrary to the standard of care outlined by all of the
    leading national and international medical and surgical associations involved with
    the treatment of obesity, as well as the current recommendations of the National Institutes
    of Health.

d) The American Medical Association considers “obesity” a disease, and denying
    standard of care treatment to people suffering from obesity is clearly discriminatory
    toward that group of people.
The scope of the problem: Obesity is the second leading cause of preventable deaths in the United States. The National Health and Nutrition Examination Survey, published in JAMA in 2014\(^1\), showed 69% of adults in the United States are overweight or obese. Current treatment guidelines for bariatric surgery include patients with BMI’s of ≥35. As shown on Figure 1, this includes 14.5% of the adult population.

Figure 1 (Data from National Health & Nutrition Examination Survey; JAMA, 2014)

<table>
<thead>
<tr>
<th>Adults in the United States 2011 - 2012</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy BMI</td>
</tr>
<tr>
<td>18 – 24.9</td>
</tr>
<tr>
<td>Overweight</td>
</tr>
<tr>
<td>25 – 29.9</td>
</tr>
<tr>
<td>Class I Obesity</td>
</tr>
<tr>
<td>30 – 34.9</td>
</tr>
<tr>
<td>Class II Obesity</td>
</tr>
<tr>
<td>35 – 39.9</td>
</tr>
<tr>
<td>Class III Obesity</td>
</tr>
<tr>
<td>40 – 49.9</td>
</tr>
<tr>
<td>Super Obesity</td>
</tr>
<tr>
<td>≥ 50</td>
</tr>
</tbody>
</table>

Obesity results in dramatic increases of myriad conditions as shown in Figure 2, which are improved or eliminated after bariatric surgery. As a result of these obesity-related comorbid conditions, the mortality rate increases dramatically with progressive increases in BMI. Figure 3 demonstrates the striking increase in mortality, both in smokers and non-smokers, with increasing obesity\(^2\). As will be subsequently discussed, bariatric surgery, in addition to improving comorbidities, also significantly improves rates of survival.

Figure 2
The broad medical community fully recognizes the seriousness of the obesity problem. The current edition of the textbook *Harrison’s Principles of Internal Medicine*, in its section on obesity, states “obesity and overweight together are the second leading cause of preventable death in the United States, accounting for 300,000 deaths per year.” “A 20-30-year-old with a BMI >45 may lose 13 years of life.”

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3 | Page
What are the outcomes following bariatric surgery?

Multiple studies have consistently shown the degree of weight loss to be several fold greater with bariatric surgery vs. non-surgical management. In a recently completed (April 2015) Health Technology Assessment regarding bariatric surgery conducted by the Washington State Health Care Authority, the relevant studies were placed into a meta-analysis (Figure 4). The superiority of weight loss with surgery vs. medical management is considerable and consistent.  

Figure 4 (Meta-analysis of mean BMI at study end: bariatric surgery vs. nonsurgical management)  

<table>
<thead>
<tr>
<th>Study name</th>
<th>Difference in means</th>
<th>Standard error</th>
<th>Variance</th>
<th>Lower limit</th>
<th>Upper limit</th>
<th>Z-Value</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kramuddin 2013</td>
<td>-5.800</td>
<td>0.658</td>
<td>0.432</td>
<td>-7.089</td>
<td>-4.511</td>
<td>-8.821</td>
<td>0.000</td>
</tr>
<tr>
<td>Kashyap 2013</td>
<td>-9.200</td>
<td>1.014</td>
<td>1.028</td>
<td>-10.188</td>
<td>-8.212</td>
<td>-7.086</td>
<td>0.000</td>
</tr>
<tr>
<td>Kashyap b 2013</td>
<td>-7.400</td>
<td>1.035</td>
<td>1.071</td>
<td>-9.428</td>
<td>-5.372</td>
<td>-7.150</td>
<td>0.000</td>
</tr>
<tr>
<td>Leonetti 2012</td>
<td>-11.500</td>
<td>1.344</td>
<td>1.805</td>
<td>-14.133</td>
<td>-8.867</td>
<td>-5.559</td>
<td>0.000</td>
</tr>
<tr>
<td>Liang 2013</td>
<td>-5.870</td>
<td>0.335</td>
<td>0.112</td>
<td>-6.526</td>
<td>-5.214</td>
<td>-17.538</td>
<td>0.000</td>
</tr>
<tr>
<td>Mingrone 2012</td>
<td>-13.760</td>
<td>1.602</td>
<td>2.567</td>
<td>-16.900</td>
<td>-10.620</td>
<td>-8.588</td>
<td>0.000</td>
</tr>
<tr>
<td>O'Brien 2006</td>
<td>-5.100</td>
<td>0.594</td>
<td>0.352</td>
<td>-6.263</td>
<td>-3.937</td>
<td>-8.593</td>
<td>0.000</td>
</tr>
<tr>
<td>Raffaelli 2014</td>
<td>-8.520</td>
<td>1.637</td>
<td>2.680</td>
<td>-11.729</td>
<td>-5.311</td>
<td>-5.204</td>
<td>0.000</td>
</tr>
<tr>
<td>Schauer 2012</td>
<td>-7.400</td>
<td>0.640</td>
<td>0.410</td>
<td>-8.655</td>
<td>-6.145</td>
<td>-11.555</td>
<td>0.000</td>
</tr>
<tr>
<td>Scopinaro 2011</td>
<td>-4.900</td>
<td>0.756</td>
<td>0.572</td>
<td>-6.382</td>
<td>-3.418</td>
<td>-6.479</td>
<td>0.000</td>
</tr>
<tr>
<td>-7.400</td>
<td>0.611</td>
<td>0.374</td>
<td>-8.599</td>
<td>-6.202</td>
<td>-12.102</td>
<td>0.000</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: $\tau^2 = 2.81; Q=55.8; df=9; I^2=84\%$  
Test for overall effect: $Z=-12.1$ (p<0.001)

The Swedish Obese Subjects Trial, now with follow-up of over 20 years, shows that surgical weight loss is well maintained over long periods of time (Figure 5).
As alluded to earlier, obesity-related comorbidities are greatly improved or resolved following surgery. Figure 6 presents an overview of studies looking at this issue.
As a result of improvements in comorbidities, there is also a very substantial improvement in survival for surgery vs. non-surgical treatment of morbid obesity. There have been three large North American trials comparing mortality rates with surgical vs. non-surgical management.

The first paper published was in 2004. Figure 7 shows the results of the Canadian study in which 1035 patients undergoing bariatric surgery were matched with an average of five control group patients with same age, sex, and BMI. In addition to dramatic improvements on the conditions listed, there was at five years an 89% reduction in death in the surgical group compared to the nonsurgical controls.6

Figure 7 (Five-Year Morbidity & Mortality Christou, 2004)6

<table>
<thead>
<tr>
<th>Condition/Disease</th>
<th>Bariatric Surgery (N = 1,035)</th>
<th>Nonsurgical Controls (N = 5,748)</th>
<th>% Change in Risk Surgery vs. Non-surgical Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>2.03%</td>
<td>8.49%</td>
<td>↓ 76%</td>
</tr>
<tr>
<td>Cardiovascular &amp; Circulatory</td>
<td>4.73%</td>
<td>26.69%</td>
<td>↓ 82%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>9.47%</td>
<td>27.25%</td>
<td>↓ 65%</td>
</tr>
<tr>
<td>Respiratory</td>
<td>2.71%</td>
<td>11.36%</td>
<td>↓ 76%</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>4.83%</td>
<td>11.9%</td>
<td>↓ 59%</td>
</tr>
<tr>
<td>Infections Diseases</td>
<td>8.7%</td>
<td>37.33%</td>
<td>↓ 83%</td>
</tr>
<tr>
<td>Mortality</td>
<td>0.68%</td>
<td>6.17%</td>
<td>↓ 89%</td>
</tr>
</tbody>
</table>

The second study was published in August 2007 in the New England Journal of Medicine. This is a U.S. study comparing outcomes in Roux-en-Y gastric bypass patients vs. a matched control group with an average follow-up of 7.1 years (Figure 8)15. This shows substantial improvement in the surgical cohort in terms of mortality with several comorbidities, as well as all-cause mortality.

Figure 8 (Adams et al., NEJM, Aug 23, 2007)15
The most recent study comparing outcomes of surgical vs. 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 9).

Figure 9: Nationwide VA Hospital Study: Bariatric Surgery Cuts Death Rate Nearly in Half vs. Matched Controls (January 2015) (Arterburn, et al. JAMA 2015)

This study shows that the death rate was cut close to half in the surgical group vs. 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.

In an attempt to improve patient safety and outcomes in bariatric surgery, the American Society for Metabolic and Bariatric Surgery (ASMBS) and the American College of Surgeons (ACS) independently established the Bariatric Surgery Centers of Excellence in 2005. In 2014, ASMBS and ACS merged their Center of Excellence programs, renaming them the Metabolic and Bariatric Accreditation and Quality Improvement Program (MBSAQIP). Presently, all private insurers require that bariatric surgery be performed at Centers of Excellence, either the MBSAQIP centers or lists of centers closely approximating the MBSAQIP centers (eg. BCBS Blue Distinction Centers). There are currently 608 MBSAQIP Centers of Excellence in the United States, 14 of which are in Minnesota.

14 MBSAQIP Centers in Minnesota

- Abbott Northwestern Hospital, Minneapolis
- Cuyuna Regional Medical Center, Crosby
- Essentia Health, Duluth
- Fairview Southdale, Edina
- Hennepin County Medical Center, Minneapolis
- May Clinic – St. Mary’s Hospital, Rochester
- Park Nicollet Methodist Hospital, St. Louis park
- St. Cloud Hospital, St. Cloud
- CHI St. Joseph’s Health, Park Rapids
- St. Joseph’s Hospital, St. Paul
- St. Luke’s Hospital, Duluth
- United Hospital, St. Paul
- Unity Hospital, Fridley
- University of Minnesota Medical Center, Fairview, Minneapolis
In a literature review, Buchwald\textsuperscript{17} reported the bariatric surgery 30-day operative mortality from 1990-2003 to be 0.55%. This relatively high mortality was one of the issues prompting the formation of Bariatric Surgery Centers of Excellence (COE). In this regard the COE system has been a huge success. Figure 10 shows the 30-day mortality in the ASMBS Centers of Excellence from June 2007-May 2009 was reported at 0.09% (less than 1/1000).\textsuperscript{18} This 30-day operative mortality rate is better than the nationwide mortality rate for many simpler surgical procedures, such as cholecystectomy.

Figure 10: ASMBS Bariatric Outcomes Longitudinal Database June 2007-May 2009 57,918 Bariatric Surgeries\textsuperscript{18}

| 30-day Mortality |  |
|------------------|--|---|
| N                | %  |
| 52               | 0.09 |

<table>
<thead>
<tr>
<th>90-day Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
</tr>
<tr>
<td>65</td>
</tr>
</tbody>
</table>

**What are the costs of bariatric surgery?**
Studies looking at the cost of bariatric surgery have consistently shown that bariatric surgery over quite a small number of years results in substantial cost savings. Figures 11, 12, 13, 14 and 15 outline these documented savings.

Figure 12: Finkelstein E, Trogdon J, Choen J, Dietz W. “Annual Medical Spending Attributable to Obesity: Payor and Service Specific Estimates” Health Affairs-Web Exclusive 27 July 2009: 822-31.

Figure 13: Nguyen N, Varela E, Sablo A, Naim J, Stamos M, Wilson S. “Reduction in Prescription Medication Costs after Laparoscopic Gastric Bypass” The American Surgeon 72 October 2006: 853-56.
Figure 14: Nguyen N, Varela E, Sablo A, Naim J, Stamos M, Wilson S. “Reduction in Prescription Medication Costs after Laparoscopic Gastric Bypass” The American Surgeon 72 October 2006: 853-56.


Health Partners is headquartered in Bloomington, Minnesota, and is one of the dominant health care insurers in Minnesota. In 2009 it looked at the costs/savings of bariatric surgery. Bariatric surgeries in the Health Partners system were performed in centers they selected, and largely mirrored the ASMBS and ACS COE list. The key finding of the study was “At 3.5 years after surgery, surgical costs had been recouped for patients undergoing gastric bypass surgery, and by year two, they had incurred fewer costs than the obese health plan population.” The abstract of this study is Figure 17.
Maryland looked at the cost of adding bariatric surgical coverage in its small group plans (Figure 18). The findings were as follows: “We estimate the cost of covering bariatric surgery at approximately $1.50 to $2.50 per month in the small group market. This data is specific to Maryland but includes data on the entire population, including those with health coverage from public sources such as Medicaid and Medicare.”

**Figure 18: Estimated Costs of Adding Bariatric Surgical Coverage to Small Group Policies – Maryland** (Retrieved from: [http://mhcc.maryland.gov/smallgroup/bariatricsurgery.pdf](http://mhcc.maryland.gov/smallgroup/bariatricsurgery.pdf))

<table>
<thead>
<tr>
<th></th>
<th>Low</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Utilization per 100,000 adults</td>
<td>68</td>
<td>119</td>
</tr>
<tr>
<td>Cost per surgery, including complications and pre- and post-surgery care</td>
<td>$27,500</td>
<td>$27,500</td>
</tr>
<tr>
<td>Cost per adult per month</td>
<td>$1.56</td>
<td>$2.72</td>
</tr>
<tr>
<td>Average number of members per audit</td>
<td>1.33</td>
<td>1.33</td>
</tr>
<tr>
<td>Claim cost per month</td>
<td>$1.17</td>
<td>$2.04</td>
</tr>
<tr>
<td>Small group market loss ratio</td>
<td>80%</td>
<td>80%</td>
</tr>
<tr>
<td>Premium impact per member per month</td>
<td>$1.46</td>
<td>$2.55</td>
</tr>
</tbody>
</table>
National and international standards of care regarding access to bariatric surgery

As the AMA considers obesity a disease, it seems obvious that health plans set up on the ACA exchanges should provide “standard care for the treatment of obesity,” especially for a disease representing the “second leading cause of preventable deaths in the U.S.” A review of the key statements of standards of care regarding obesity follows.

In March 2011, the International Diabetes Federation published a position statement titled “Bariatric Surgical & Procedural Interventions in the Treatment of Obese Patients with Type 2 Diabetes.” 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 T2 DM; 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 β-cell function characteristic of T2 DM.”

The American Diabetes Association’s “Standards of Care in Diabetes” 2015 states:

a) Executive Summary: “Bariatric surgery may be considered for adults with BMI>35 kg/m² and type 2 diabetes, especially if the diabetes or associated comorbidities are difficult to control with lifestyle and pharmacologic therapy.”
b) In the 2015 ADA Standards of Care, the superiority of surgery is specifically referenced: “Treatment with surgery has been shown to achieve near or complete normalization of glycaemia two years following surgery in 72% of patients compared with 16% in a matched control group treated with lifestyle and pharmacological interventions.”

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.
Figure 19

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

Figure 19 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” Figure 21 highlights that the recommendation has a grade of “A” (highest possible grade). There is no equivocating here; a health policy not covering bariatric surgery is inconsistent with the standards of care of the National Institutes of Health.
Box 13: Standard care AHA/ACC/TOS guidelines require access to bariatric surgery.

**Figure 20 Legend:**
Treatment Algorithm—Chronic Disease Management Model for Primary Care of Patients With Overweight and Obesity*  
*This algorithm applies to the assessment of overweight and obesity and subsequent decisions based on that assessment. Each step (designated by a box) in this process is reviewed in Section 2.2 and expanded on in subsequent sections.
†BMI cutpoint determined by the FDA and listed on the package inserts of FDA-approved obesity medications. BMI indicates body mass index; CVD, cardiovascular disease; and FDA, U.S. Food and Drug Administration.
The following additional professional society guidelines consistently recommend that bariatric surgery be a treatment option for individuals with a BMI of > 40 kg/m² or > 35 kg/m² with significant comorbidities.

- The Institute for Clinical Systems Improvement (ICSI) 2013
- Veterans Administration (VA) Management of Overweight and Obesity Working Group (2014)
- Australian National Health and Medical Research Council (2013)
- National Institute for Health and Care Excellence, UK (NICE) 2014
- American Association of Clinical Endocrinologists, Obesity Society, American Society for Metabolic and Bariatric Surgery (2013)
The most recent guidelines relating to bariatric surgery were published in August 25, 2015 in “Circulation.” This was an American Heart Association/American Diabetes Association statement entitled “Update on Prevention of Cardiovascular Disease in Adults with T2 Diabetes in Light of Recent Evidence.” This likewise includes a recommendation that adults with BMI > 40 or >35 with comorbidities be considered for bariatric surgery.

Finally, the Washington State Health Care Authority (April 10, 2015) and the Oregon Health Authority (September 10, 2015 – draft) both undertook comprehensive “health technology assessments” and have, from a public payor perspective, recommended that their state exchange policies cover bariatric surgery in adults, using the current NIH guidelines (BMI > 40 or >35 with comorbidities).

At this point there can be no question: For any health plan to be consistent with the international and national standards of care, it must include bariatric surgery as a covered service.

One final consideration is that withholding bariatric coverage must be viewed as highly discriminatory towards obese individuals. We know that no other significant medical/surgical condition which well established, highly efficacious/lifesaving care is not covered. To not provide coverage for bariatric surgery is unethical and clearly discriminating toward obese citizens.

Summary

1. Overweight and obesity:
   a. 2nd leading cause of preventable death
   b. Results in enormous societal economic costs

2. For morbid obesity, surgery is the only current treatment resulting in significant:
   a. Elimination of or reduction in severity of weight-related comorbid diseases
   b. Improvements in survival

3. Costs related to surgery for obesity:
   a. ROI reached in 2-4 years post-operatively
   b. Cost of including insurance coverage for morbid obesity is quite modest, especially considering the enormity of the problem of obesity

4. Current standard of medical care (IDF, ADA, AHA/ACC/TOS, etc) all include bariatric surgery as part of their treatment guidelines.

NOT covering bariatric surgery = NOT providing coverage consistent with current national and international standards of care.
5. Not covering bariatric surgery is withholding well established, standard care for a highly lethal disease, and can only be viewed as highly discriminating toward the obese population.

Based on this review the Minnesota Chapter of the ASMBS strongly urges that bariatric surgery coverage for adults be included in the Minnesota 2017 Benchmark Plan. Presumably, the patient eligibility criteria and facilities/surgeons providing these services would be the same for a given health insurer’s policies that cover bariatric surgery.

It is notable that the federal Office of Personnel Management (OPM) encourages all Federal Employee Health Benefit (FEHB) Program carriers and Multi-state Health Plans to provide patient access to the full range of obesity treatment options (including bariatric surgery). Thus, those at the federal level evaluating this issue agree that bariatric surgery should be a covered service. Looking at the big picture, looking at the federal OPM’s position and the findings of this review and the multiple other reviews cited, and the expectation that a large portion of the population should not be discriminated against in their insurance coverage, it seems reasonable to request consideration that HHS/CMS go a step further and list bariatric surgery coverage as a required component of ACA Exchange Policies nationwide.

Thank you very much for your consideration.
References


3) Harrison’s Principles of Internal Medicine, 19th Edition (2015), page 415e-6


