September 7, 2011

Dear Governor/Commissioner Nathan Deal and David Cook:

We are requesting reconsideration of the decision to deny coverage of weight loss surgery for the Georgia State Health Benefit Plan. We fully appreciate the severe fiscal challenges you face each day and ask you to restore coverage for a treatment that is safe and effective for Georgians. Evidence demonstrates that bariatric surgery saves money with a reduction in health care costs. Bariatric surgery’s safety and efficacy have convinced Medicare, Private carriers, 48 Medicaid programs, 43 State Employee Plans and Federal health plans such as the Federal Employee Health Plan and Tricare to provide this benefit. It should be noted that three of your current plans (Medicare Advantage Standard/Medicare Advantage Premium/Tricare Supplement) provide coverage on a national basis.

It is note-worthy that Georgia is a leader in bariatric surgery and the American Society of Metabolic and Bariatric Surgeons President-Elect is Georgia’s own Dr. Jaime Ponce from Dalton, GA. As you can see below, the entire bariatric surgery community is committed to the care of the obese patient and full access to care for this population in need. We all ask that you do not support the exclusion of weight loss surgery given the undeniable safety and efficacy of this needed intervention.

We are all aware that obesity is the leading public health concern in both the United States and Georgia. Nationally, Georgia ranks #17 in Obesity at 28.7%, #11 in Hypertension at 29.5%, and #12 in Diabetes at 9.7% (http://healthyamericans.org). With 75,000 state employees, teachers, retirees and school personnel, the State Health Benefit Plan is an important investment in health including approximately 7500 diabetics in the plan. With a low turnover rate of 14%, average age of 45 and average tenure of 10 years, the average state employee requires a long-term perspective regarding health care choices (http://www.spa.ga.gov).

Weight loss surgery represents a safe, effective and enduring response to obesity as noted below:

- **Untreated obesity consumes a substantial portion of any health care budget** specifically in GA where over $4.2 billion obesity-attributable expenditures was spent in 2009 according to Trogdon in *Obesity* June 2011. Treatment of obesity affords the ability to cap and lower this cost through successful intervention.
• Bariatric surgery’s effect on comorbidities is powerful and pervasive with an 82% remission of diabetes and similarly good results for other previously chronic conditions such as hypertension, hyperlipidemia, and sleep apnea.

• An Archives of Surgery study found health care costs specific to diabetes declined by 70% in three years following bariatric surgery with numerous medical studies substantiating that bariatric surgery can result in over-all cost savings for these patients who require numerous medications, clinic visits, and hospitalizations prior to bariatric surgery.

• An analysis by Crimeaux of a private payer database showed that cost savings associated with bariatric surgery began accruing as early as 3 months after surgery with downstream savings offsetting the initial costs in 2 years. This is an important consideration given the stability and loyalty of the State Employees Health Benefit population regarding its health care coverage.

• A group in Texas used a regional economic model to estimate the economic impact of lost productivity due to morbid obesity and the net benefit of bariatric surgery to the region. They found that bariatric surgery provided immediate benefit to the region’s economy by decreasing lost workdays and they concluded that the treatment costs associated with bariatric surgery were small relative to the economic losses of not treating obesity.

• Bariatric surgery in the United States and Georgia remains profoundly safe as supported by the nation’s largest bariatric surgery database, BOLD ® (Bariatric Outcomes Longitudinal Database). In 2009-2010, national and Georgia 30 Day mortality was 0.1 % which is equivalent to gallbladder removal and hip replacement surgery.

• In a New England Journal of Medicine article, obese patients who had bariatric surgery had a 40% reduction in mortality versus obese patients who did not have surgery. In 2009, 2785 Georgians and 21 Georgia State Employees underwent bariatric surgery. Without surgery, 1,114 Georgians and 8 Georgia State employees may die in the next five years without the life-saving intervention of bariatric surgery.

It is very clear that if bariatric surgery is not covered, then costs will not decline—costs will rise. On August 11, 2011, the Board of the Department of Community Health reviewed a new proposed coverage plan for the State Health Benefit Plan. The new proposal is to be applauded for emphasizing Wellness through the provision of tobacco cessation therapy and collection of BMI, Blood Pressure, Cholesterol, and Glucose data. As cited in the August presentation, tobacco cessation has a success rate of 19.6%. In stark contrast, bariatric surgery’s success rate is considerably higher and more reliably achieved upon weight (50-70%
Excess Weight Loss), hypertension (70% remission), hyperlipidemia (63% remission) and diabetes (82% remission).

From 2009 Georgia-specific data from the BOLD database, 2785 Georgians and approximately 21 state employees underwent bariatric surgery with 62% with Hypertension, 37% with Hyperlipidemia, and 32% with Diabetes. In examining Diabetics alone and taking into account a well-proven 82% remission rate, 731 previously obese and diabetic Georgians and 12 Georgia state employees will no longer require diabetic medications and/or attendant hospital and clinic visits! This is a very significant cost-savings to payors with a 2 year perspective.

Bariatric surgery can provide tertiary prevention of the progression of these chronic medical conditions by alleviating disease and lowering costs. By collecting data BMI data and not providing available and effective therapy, the current proposal disenfranchises patients in need. If tobacco cessation is provided, then correspondingly bariatric surgery should also be provided. The only other service that is planned to be removed is $200 dollars for eyeglasses that clearly does not have the same impact on health as bariatric surgery. In a budget of $2,909,813,798, it is doubtful that exclusion of bariatric surgery for 54 Georgia State Employees will be impactful upon the bottom line and will clearly be harmful to those in need and actually have the potential of raising cost.

**Recommendation**

We and our patients would be most grateful if you could restore coverage of this vitally important therapy for patients in need. In keeping with the Centers of Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) for Bariatric Surgery for Treatment of Morbid Obesity (100.1) since 2006, bariatric surgery for Georgia State Health Employees Plan beneficiaries should be covered for those individuals with a BMI ≥ 40 or a BMI ≥ 35 with significant comorbidities. This should apply to patients who are acceptable medical risks and capable of understanding the surgery and its outcomes. Please consider this request favorably and do not hesitate to contact us with questions or concerns.
Sincerely,

Robin Blackstone, MD, FACS, FASMBS
President, American Society for Metabolic and Bariatric Surgery

Jaime Ponce, MD, FASMBS
President-Elect, American Society for Metabolic and Bariatric Surgery

John Morton, MD, MPH
Chair, Access to Care, American Society for Metabolic and Bariatric Surgery

GA Surgeons
Supporting Evidence: Efficacy

As long ago as 1991, the National Institutes of Health determined that “diets, exercise, behavioral modification and drugs are not effective therapies for severely obese patients with a body mass index \( \geq 35 \) (BMI=M²/Kg)”, i.e. those who exceed their ideal weight by about 100 lbs. Accordingly, since 2004, CMS/Medicare and virtually every private carrier has adopted the guideline that surgery is the standard of care for patients with a BMI \( \geq 40 \) or a BMI \( \geq 35 \) with significant complications such as diabetes. Evidence supporting the decision to approve surgery for obesity is solid. For example, the gastric bypass operation produces

- **Durable weight loss** with a mean weight loss of 106 lbs. (In a series of 834 patients followed as long as 16 years with a 95% followup\(^1\)).
- **Full and durable remission of type 2 diabetes** in 83% of the patients\(^2\).
- **Reduction in mortality from diabetes** by 78%\(^3\).
- **Full and durable remission of the diseases associated with obesity** hypertension (63.3%), sleep apnea (68.9%), hyperlipidemia (61.4%), asthma (66%), gastroesophageal reflux disease (87.6%), and arthritis of the weight bearing joints (61.4%)\(^4,5\).
- **A reduction of the prevalence of cancer** by 80% within five years\(^6\).

Table 1 documents the health effects of patients who have undergone metabolic surgery compared with those who were denied surgery. During the 36 months of observation of those denied surgery, an additional 9.2% developed diabetes, another 41.9% became hypertensive while the operated group resolved most of their co-morbidities and very few progressed in these diseases.

The table also confirms that delay of the surgery may prevent the chance for full recovery. In the seven months delay waiting for the surgery, another 41% developed hypertension. Delay is, similarly, harmful in patient with diabetes. Those who have diabetes for less than seven years,
for example, are far more likely to progress to full remission than patients who have had diabetes for over ten years.

**Evidence of cost effectiveness**

Metabolic surgery is cost-effective. Choosing surgery as the approach to treat metabolic disease brings significant savings to Medicaid, primarily due to a marked decrease in the use of prescription drugs. In addition, many of the surgery patients are able to function again and choose to return to work. Again, the evidence is solid.

- The full remission of diabetes in 83% of the patients is followed by total or almost full cessation of drug use (Fig.2)\(^7\).
- There is general agreement among health care economists\(^8,9,10,11\) that the cost of surgery is amortized within two to three years. Makry et al. reported that the annual cost of patients with diabetes dropped from $10,592 in the year prior to surgery to $1,878/yr within two years\(^7\). Due to the reduced reimbursements by Medicaid, the amortization may well be complete in less than one year.

**Evidence of Safety**

Due to the demanding requirements that designation as a Center of Excellence has provided metabolic surgery, the operations are now performed as safely as a routine gall bladder operation with a 90 day mortality rate of 0.1% despite the fact that the care of these sick patients is technically challenging and medically demanding\(^12\). Over 650 hospitals in the U.S. and additional facilities in 17 countries have now met these credentials, documented with site inspections and full reporting of all cases. By comparison, the mortality in morbidly obese patients with non-operative approaches is 4.5 times as high as that achieved by surgical care.

**A REVIEW OF THE COST EFFECTIVENESS OF BARIATRIC SURGERY**

**Executive Summary:**

Considerable evidence has proven that bariatric surgery, now increasingly known as “metabolic” surgery, has dramatic effects on the improvement of health beyond weight loss. Bariatric surgery:

- Is the only treatment that produces durable and full remission of a number of fatal diseases including type 2 diabetes (T2D), hypertension, sleep apnea, gastro-esophageal reflux disease (GERD), adult onset asthma as well as such crippling disorders as degenerative arthritis of weight bearing joints\(^13\).
- Reduces the prevalence of cancers associated with obesity including malignancies of the breast, colon, ovary and prostate\(^14\).
• Reduces mortality of severe obesity and of diabetes by 80 percent\textsuperscript{15,16}.
• Makes it possible for individuals on disability to return to work.\textsuperscript{17} Returning these patients to the work place also frees family members who could not hold jobs due to care responsibilities.

• With the mortality rate of 4.5\% per year without the surgery compared to 1.0\% per year after surgery, it is likely that at least three of every 100 patients denied surgery will lose their lives in the next year due to deaths that could otherwise be prevented by surgery. Furthermore, those who survive will suffer further progression of their disease.

**Surgery vs. Medical Treatment for Obesity and Type 2 Diabetes**

The advantages of the surgical approaches are so well-documented in terms of durable weight loss, the full, long-term remission of co-morbidities, and the reduction in mortality. In addition, delay of the surgery decreases its efficacy. Patients with a history of diabetes that is less than seven years have a significantly higher chance for full remission than those who have had the disease for a longer duration\textsuperscript{18}.

A prospective, randomized study comparing the costs and outcomes of a surgical vs. a medically treated cohort was completed in Australia by Keating et al\textsuperscript{19}. They concluded that surgical therapy (laparoscopic adjustable gastric banding) was a cost-effective option for managing T2D in class I and II obese patients. The incremental cost-effectiveness ratio for surgical therapy was 16,600 AUD per case of diabetes remitted (currency exchange: 1 AUD = 0.74 USD).

**A Review of the Literature Evaluating the Cost Effectiveness of Metabolic Surgery**

An extensive review of the literature concerning the impact of bariatric surgery on the cost of care of morbidly obese patients is summarized in Table 1. Highlights from this review are below. There is broad agreement that bariatric surgery is a cost effective treatment for morbid obesity and its associated comorbidities.

• An analysis of a private payer database showed that cost savings associated with bariatric surgery began accruing as early as 3 months after surgery although downstream savings were estimated to offset the initial costs in 2 to 4 years.\textsuperscript{20}

• The results obtained from a two-year randomized controlled trial comparing bariatric surgery to conventional therapy for the treatment of morbidly obese diabetic patients were used to model lifetime costs of the two treatment regimes. Bariatric surgery was found to deliver a mean health care savings of 2,400 AUD and 1.2 additional QALYs (quality-adjusted life-years) per patient relative to conventional therapy.\textsuperscript{21}
• Claims data were used to examine the impact of bariatric surgery on medication utilization and annual health costs in morbidly obese patients with type 2 diabetes. Total annual health costs were found to increase 9.7% in the first year after surgery but then decreased by 34.2% and 70.5% in years 2 and 3 after surgery.  

• Claims data were also used in combination with patient surveys to assess the cost, quality of life impact and cost-utility of Roux-en-Y gastric bypass surgery in a managed care population. Bariatric surgery was found to dramatically improve health-related quality of life and to be cost-effective over a lifetime ($1400/quality-adjusted life years gained).  

• A predictive health economic model (the CORE Diabetes Model) was used to assess the cost-effectiveness of gastric bypass compared to medical management in morbidly obese patients with type 2 diabetes. Base case analysis showed that bariatric surgery improved life expectancy relative to medical management with increased short-term medical costs however at an acceptable level of cost-effectiveness ($21,973 /quality-adjusted life years gained).  

• In a similar manner, the CDC-RTI Diabetes and Cost-Effectiveness Model was used to analyze the cost-effectiveness of bariatric surgery in morbidly obese diabetics. Again, overall medical costs were found to increase however, at cost-effectiveness ratios of $7,000-$12,000/quality-adjusted life years for gastric bypass and $11,000-$13,000 for gastric banding surgery. Hoerger et al  

• A group in Texas used a regional economic model to estimate the economic impact of lost productivity due to morbid obesity and the net benefit of bariatric surgery to the region. They found that bariatric surgery provided immediate benefit to the region’s economy by decreasing lost workdays and they concluded that the treatment costs associated with bariatric surgery were small relative to the economic losses of not treating obesity. Ewing et al
### TABLE 1

Studies Examining the Impact of Bariatric Surgery on Cost of Care

<table>
<thead>
<tr>
<th>Objective</th>
<th>Population</th>
<th>Methods</th>
<th>Clinical Effects</th>
<th>Cost Implications</th>
<th>Conclusions</th>
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<tr>
<td><strong>Abbreviations:</strong> QALY – quality-adjusted life years; T2D – type 2 diabetes; QOL – quality of life; AUD – Australian dollar; GBP – gastric bypass; AGB – adjustable gastric banding</td>
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#### A Study on the Economic Impact of Bariatric Surgery

Evaluated the private 3rd party payer return on investment for bariatric surgery.

*Cremieux et al, Am J Manag Care 2008; 14:589*

| 3651 bariatric surgery patients and 3651 matched surgery-eligible control subjects identified using the Ingenix private administrative claims database, 73% GBP (open), 12% GBP (laparoscopic), 4% other laparoscopic, 1999-2005 | • Assessed total healthcare costs for surgery patients and controls for 6 month prior to surgery and up to 5 years post-surgery. | • Mean cost of bariatric surgery ranged from $17,000 (laparoscopic) to $26,000 (open). |
| **None reported** | • Applied a Tobit model to account for differences in patient characteristics. | • Cost savings associated with bariatric surgery began accruing as early as 3 months after surgery. |
| • Calculated a return on investment based on the resulting coefficients using a 3.07% discount rate. | • At 18 months post-surgery, the mean monthly savings associated with bariatric surgery was $500 for the whole sample. | • At 13 months post-surgery, savings reached >$900 for laparoscopic procedures. |

### Cost-Effectiveness of Surgically Induced Weight Loss for the Management of Type 2 Diabetes: A Randomized Controlled Trial

To determine the within-trial cost-efficacy of surgical therapy relative to conventional therapy for achieving remission of recently diagnosed (<2 yrs) T2D in class I and II obese patients.

*Keating et al, Diabetes Care 2009;32:580*

| 60 obese patients (BMI >30 and <40 kg/m2), 30 receiving a AGB and 30 received the best available medical management for T2D in Australia. Patients followed for 2 years. | • Diabetes remission was achieved by 73% of the surgical group and 13% of the conventional group. | • Relative to conventional therapy, the incremental cost-effectiveness ratio for surgical therapy was 16,600 AUD (1 AUD = 0.74 USD) per case of diabetes remitted. The comparable ICER for conventional therapy relative to no intervention is 25,500 AUD per case of diabetes remitted for the same time period. |
| Direct costs of interventions implemented in the trial were used. No discounting applied. | • Mean weight loss was 20.7% for the surgical group and 1.7% for the conventional therapy group. | • Mean 2-year intervention costs per patient were 13,400 AUD for surgical therapy and 3,400 AUD for surgical therapy. |

Surgical therapy is a cost-effective option for managing T2D in class I and II obese patients.
Cost-Effectiveness of Surgically Induced Weight Loss for the Management of Type 2 Diabetes: Modeled Lifetime Analysis

To estimate the long-term cost-effectiveness of surgical therapy relative to conventional therapy for the management of T2D in class I and II obese patients.

Keating et al, Diabetes Care 2009;32:567

- Study builds on the within-trial cost-efficacy analysis (above) by comparing the lifetime costs and QALYs between the two intervention groups.
- Intervention costs were extrapolated based on observed resource utilization during the trial.
- Health care costs and outcomes required to derive estimates of QALYs were obtained from the literature.
- A Markov model was used to extrapolate the costs and outcomes observed over the 2-year period to the lifetime of the trial population.

The mean number of years of diabetes remission over a lifetime predicted by the model:
- 11.4 years for surgical therapy
- 2.1 years for conventional therapy

During the remainder of their lifetime, surgical and conventional therapy patients lived 15.7 and 14.5 discounted QALYs, respectively.

The mean discounted lifetime costs were:
- 98,900 AUD per surgical therapy year
- 101,400 AUD per conventional therapy year.

Relative to conventional therapy, surgically induced weight loss was associated with a mean health care saving of 2,400 AUD and 1.2 additional QALYs per patient.

Medication Utilization and Annual Health Care Costs in Patients with Type 2 Diabetes Mellitus Before and After Bariatric Surgery

Examined the impact of bariatric surgery on the use of diabetes medication and on total health care costs.

Makary et al, Arch Surg 2010;145:726

- 2235 adults with T2D identified from claims data, 2002-2005
- Evaluated total direct health care costs paid by the insurer for health care claims at 3 and 6 months before surgery, at the time of surgery, and at 6, 9, 12, 24 and 36 months after surgery.
- Use of diabetes medication decreased significantly after surgery to 25.3%, 19.4% and 15.5% at 6 months, 1 and 2 yrs.
- Total annual health costs increased by 9.7% in year 1 after surgery but then decreased by 34.2% in year 2 and by 70.5% in year 3.

Bariatric surgery is associated with reductions in the use of medication and in overall health care costs in patients with T2D.

A Cost-Benefit Analysis of Bariatric Surgery on the South Plains Region of Texas

Examined impact of lost productivity due to obesity in region of TX and the net benefit of bariatric surgery to the region.

- 150 morbidly obese undergoing lap RYGBP or AGB surgery in South Plains region of TX, 2003-2005
- Applied an input-output model to estimate economic impact utilizing data from Bureau of Labor Statistics and Bureau of Economic Analysis used.
- Obese workers are less productive due to fewer days at work.
  - Pre-surgery, patients lost 33 ± 10 days of work due to illness or injury in the time period studied
  - Post-surgery patients lost 1 ± 4
- Effects of morbid obesity on
  - Total output lost: $364 mil
  - Total labor income lost: $59 mil
  - Jobs lost or not sustained: 1,977
- Estimated net benefit of bariatric

Surgically induced weight loss saves health care costs and generates health benefits in recently diagnosed T2D patients.
<table>
<thead>
<tr>
<th>Ewing et al, Obesity Surgery 18 Sep 2010</th>
<th>days</th>
<th>surgery in terms of gains in lost output (at given discount rate):</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td>• $9.9 bil (3%)</td>
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<td>• $5 bil (5%)</td>
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<td></td>
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<td>• $1.4 bil (10%)</td>
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### The Cost, Quality of Life Impact, and Cost-Utility of Bariatric Surgery in a Managed Care Population

Assessed the cost, quality of life impact and cost-utility of bariatric surgery in a managed care population.


- 221 morbidly obese patients undergoing RYGB (64% open, 33% lap) in MI, all members of a managed care health plan, 2001-2005
- Reviewed medical claims data 18 months prior to and 24 months after bariatric surgery.
- Calculated average PMPM (per-member-per-month costs).
- Health-related QOL assessed using the EQ-5D and visual analog scale.
- Cost-utility assessed with a 2-yr and lifetime time horizon with outcome expressed as incremental cost/ QALY gained.

One year outcomes:
- BMI fell from 51 to 31 kg/m\(^2\) in women and from 59 to 35 kg/m\(^2\) in men with significant improvement in comorbidities.
- Post-surgical morbidity and mortality were low although a number of patients experienced complications requiring additional inpatient procedures.
- Health-related QOL was poor prior to surgery and improved substantially after surgery.

Effects of bariatric surgery on direct medical costs:
- Increased in the 6 mos prior to surgery (due to increased diagnostic testing)
- Decreased in the year after surgery (due to decreased outpatient pharmacy costs and diagnostic testing)
- Variable/slightly higher 12-24 mos after surgery (due to increased outpatient pharmacy and inpatient care)
- Over a lifetime, the cost-utility of bariatric surgery vs no surgery was $1400 per QALY gained.
- Shortening the time horizon to 2 and 5 years showed a much higher cost per QALY.
- Bariatric surgery was more cost-effective when performed laparoscopically, in women, non-whites and more obese patients.

### Cost-Effectiveness of Roux-en-Y Gastric Bypass in Type 2 Diabetes Patients

Assessed the cost-effectiveness of RYGB for treating type 2 diabetes (T2DM).


- 567 morbidly obese patients with T2DM undergoing RYGB in MN, 2001-2007
- Used a predictive health economic model (the CORE Diabetes Model) to estimate the lifetime costs and clinical effectiveness of RYGB compared with standard medical management of obese T2 diabetics.
- Direct medical costs and health-state utilities used to estimate QALYs.
- Significant decreases in
  - BMI (-15.1 kg/m\(^2\))
  - HbA1c (-1.5%)
  - Systolic BP (-9.9 mmHg)
  - Total Cholesterol (-17.9 mg/dL)
  - Triglycerides (-97.1 mg/dL)
- Post-surgical morbidity and mortality were low.
  - Procedure-related death – 0.5%
  - Major reoperations: 0.8% early; 0.9% late
- Base-case analysis showed that compared to medical management of T2DM, bariatric surgery improved life expectancy both adjusted and unadjusted for QOL (+0.67-0.90 years)
- Medical costs were increased but at an acceptable level of cost-effectiveness ($21,973 per QALY).
- Guideline for cost-effectiveness in U.S. is $50,000 per QALY.
- Shortening the time horizon to 5 and 10 years showed a much higher cost

Compared with medical management, RYGB is cost-effective under conservative assumptions for procedure costs and complicate rate/costs.
- Minor complications: 2.5% early, 4.0% late per QALY.

<table>
<thead>
<tr>
<th>Cost-Effectiveness of Bariatric Surgery for Severely Obese Adults with Diabetes</th>
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<tbody>
<tr>
<td>Analyzed the cost-effectiveness of bariatric surgery in morbidly obese diabetics. Hoerger et al, Diabetes Care 2010;33:1933</td>
</tr>
<tr>
<td>Used the CDC-RTI Diabetes and Cost-Effectiveness Model to analyze the cost-effectiveness of bariatric surgery (GBP and AGB) in diabetics.</td>
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<tr>
<td>Rates of diabetes remission and improvement following bariatric surgery used in the model derived from a meta-analysis.</td>
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<tr>
<td>Gastric bypass surgery had cost-effectiveness ratios of $7,000/QALY and $12,000/QALY for morbidly obese patients with newly diagnosed and established diabetes, respectively. Banding surgery had cost-effectiveness ratios of $11,000 and $13,000/QALY for morbidly obese patients with newly diagnosed and established diabetes, respectively.</td>
</tr>
<tr>
<td>Gastric bypass and gastric banding are cost-effective methods of reducing mortality and diabetes complications in morbidly obese adults with diabetes.</td>
</tr>
</tbody>
</table>
REFERENCES


5 Blackstone R. Results reported at the Annual Meeting of the American Society for Bariatric and Metabolic Surgery 2008.


