BARIATRIC & METABOLIC SURGERY
Economic Evidence Review
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This document was prepared by Ethicon US, LLC
CHAPTER 1
Bariatric and Metabolic Surgery—Background Information and Global Consensus
# Health Economic Impact of Bariatric and Metabolic Surgery: Review of Peer-Reviewed Literature and Health Technology Assessments

## Key Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>ACP</td>
<td>American College of Physicians</td>
</tr>
<tr>
<td>ADSS</td>
<td>Asian Diabetic Surgery Summit</td>
</tr>
<tr>
<td>AGA</td>
<td>American Gastroenterological Association</td>
</tr>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality (US)</td>
</tr>
<tr>
<td>BCBS TEC</td>
<td>Blue Cross Blue Shield Technology Evaluation Center (US)</td>
</tr>
<tr>
<td>BPD/DS</td>
<td>Biliopancreatic diversion with or without duodenal switch</td>
</tr>
<tr>
<td>BIM</td>
<td>Budget-Impact Model</td>
</tr>
<tr>
<td>BMI</td>
<td>Body-Mass index</td>
</tr>
<tr>
<td>BRATS</td>
<td>Brazilian Health Technology Assessment Bulletin</td>
</tr>
<tr>
<td>CADTH</td>
<td>Canadian Agency for Drugs and Technologies in Health</td>
</tr>
<tr>
<td>COE</td>
<td>Center of Excellence</td>
</tr>
<tr>
<td>CTAF</td>
<td>California Technology Assessment Forum (US)</td>
</tr>
<tr>
<td>DIMDI</td>
<td>German Institute for Medical Documentation</td>
</tr>
<tr>
<td>HAS</td>
<td>French National Authority for Health</td>
</tr>
<tr>
<td>HTA</td>
<td>Health Technology Assessment</td>
</tr>
<tr>
<td>ICER</td>
<td>Incremental Cost-Effectiveness Ratio</td>
</tr>
<tr>
<td>IDF</td>
<td>International Diabetes Federation</td>
</tr>
<tr>
<td>IECS</td>
<td>Institute for Clinical Effectiveness and Health Policy, Argentina</td>
</tr>
<tr>
<td>IFSO-APC</td>
<td>International Federation for the Surgery of Obesity and Metabolic Disorders-Asia Pacific Conference</td>
</tr>
<tr>
<td>LAGB</td>
<td>Laparoscopic Adjustable Gastric Band</td>
</tr>
<tr>
<td>LRYGB</td>
<td>Laparoscopic RYGB</td>
</tr>
<tr>
<td>LSG</td>
<td>Laparoscopic Sleeve Gastrectomy</td>
</tr>
<tr>
<td>MSAC</td>
<td>Medical Services Advisory Committee (Australia)</td>
</tr>
<tr>
<td>NICE</td>
<td>National Institute for Health and Care (formerly Clinical) Excellence (UK)</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institutes of Health (US)</td>
</tr>
<tr>
<td>NHS</td>
<td>National Health Service (UK)</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>------</td>
<td>------------</td>
</tr>
<tr>
<td>OHTAC</td>
<td>Ontario Health Technology Advisory Committee (Canada)</td>
</tr>
<tr>
<td>QALY</td>
<td>Quality Adjusted Life Years</td>
</tr>
<tr>
<td>QoL</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>SAGES</td>
<td>Society of American Gastrointestinal and Endoscopic Surgeons</td>
</tr>
<tr>
<td>ROI</td>
<td>Return on Investment</td>
</tr>
<tr>
<td>RYGB</td>
<td>Roux-en-Y Gastric Bypass</td>
</tr>
<tr>
<td>SIGN</td>
<td>Scottish Intercollegiate Guidelines Network (UK)</td>
</tr>
<tr>
<td>SG</td>
<td>Sleeve Gastrectomy</td>
</tr>
<tr>
<td>SSAT</td>
<td>Society for Surgery of the Alimentary Tract</td>
</tr>
<tr>
<td>T2DM</td>
<td>Type 2 Diabetes Mellitus</td>
</tr>
<tr>
<td>VA/DoD</td>
<td>Veteran’s Administration/Department of Defense (US)</td>
</tr>
<tr>
<td>WTP</td>
<td>Willingness to Pay</td>
</tr>
</tbody>
</table>

### Glossary of Health Economic Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>BI (Budget Impact)</td>
<td>The financial impact of the introduction of a technology or service on the capital and operating budgets of a government or agency or a hospital</td>
</tr>
<tr>
<td>CEA (Cost-effectiveness Analysis)</td>
<td>Comparison of new therapies with existing ones, or with placebo/no treatment, on both effectiveness and efficacy: costs are measured in monetary units and outcomes are measured in non-monetary units, e.g., reduced mortality or morbidity</td>
</tr>
<tr>
<td>Dominant</td>
<td>Measure of economic impact, a technique is dominant if it is both more effective and less costly than the comparator</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>The benefit (e.g., to health outcomes) of using a technology for a particular problem under general or routine conditions, for example, by a physician in a community hospital or by a patient at home</td>
</tr>
<tr>
<td>Efficacy</td>
<td>The benefit of using a technology for a particular problem under ideal conditions, for example, in a laboratory setting, within the protocol of a carefully managed randomized controlled trial, or at a “center of excellence”</td>
</tr>
<tr>
<td>Efficiency</td>
<td>The extent to which the maximum possible benefit is achieved out of available resources</td>
</tr>
<tr>
<td>ICER (Incremental cost-effectiveness ratio)</td>
<td>The additional cost of the more expensive intervention as compared with the less expensive intervention divided by the difference in effect or patient outcome between the interventions, e.g., additional cost per QALY</td>
</tr>
<tr>
<td>QALY (Quality-adjusted life year(s))</td>
<td>Measure of effectiveness, expression of how much life of years in good quality of life is gained by using a new treatment: A unit of health care outcomes that adjusts gains (or losses) in years of life subsequent to a health care intervention by the quality of life during those years. QALYs can provide a common unit for comparing cost utility across different interventions and health problems</td>
</tr>
<tr>
<td>ROI (Return on Investment)</td>
<td>Also known as the time to break-even, this is when initial spend equals the amount saved due as a result of that spend</td>
</tr>
</tbody>
</table>
Executive Summary and Key Takeaways:

- Bariatric surgery has been demonstrated to be cost-effective compared to non-surgical obesity treatment in all countries where it has been evaluated. It has also been associated with net cost savings in more than half of all cost-effectiveness studies published.
  
  i. Depending on the specific procedure evaluated, the ICER of bariatric surgery as compared to standard of care was well below the typical $50,000/QALY threshold set by most countries, specifically in the $1,771-$28,300/QALY range depending on subpopulation, technology, and country. (Song 2013, Faria 2013, Song 2013, Hashemi 2010, Wang 2013, Faria 2013, Terranova 2012)

- Bariatric surgery in patients with type 2 diabetes mellitus (T2DM) is cost-effective and more cost-saving compared to non-surgical treatment options.
  
  i. In France, German, Austria, and Italy, bariatric surgery was more cost saving over 5-year period than standard medical management of T2DM. (Terranova 2012)

  ii. In Finland, bariatric surgery was found to be both cost saving and more effective than conventional treatment. (Mäklin 2011)

  iii. In Canada, bariatric surgery was found to be both cost saving and more effective than conventional treatment. (Hashemi 2010)

  iv. In Portugal, bariatric surgery was found to be both cost saving and more effective than conventional treatment. (Faria 2013)

• Laparoscopic roux-en-y gastric bypass (RYGB) is associated with superior economic outcomes and sustained long-term weight loss compared to gastric banding.

  i. RYGB is considered by HTA agencies and other technology reviewers to be the most efficacious form of bariatric surgery due to sustained weight loss at least two years after surgery and higher rates of diabetes resolution. (OHTAC 2005, OHTAC 2009, Tice 2009, Habermann 2012, SSAT 2005, NIH 2013)

  ii. While both LAGB and RYGB showed cost savings over standard of care in relation to comorbidity resolution, RYGB was associated with greater cost savings than LAGB over a 5-year period in four representative countries as show by a review of six studies. (NHS QIS 2012, Terranova 2012)

• Pharmaceutical utilization rates are reduced in the first year following surgery, especially for patients with comorbid diabetes and cardiovascular diseases.

  i. An evaluation of US private payer claims data by AHRQ found that medication usage for obesity-related diabetes, hypertension, and hyperlipidemia fell by more than half by the 12-month point after surgery. (Segal 2010)

  ii. In a VA study, cost savings in diabetes medication ranged from 80% to 99.7% at 12 months after sleeve gastrectomy and 88% at 12 months after gastric bypass. Similarly, the annual cost of medications to treat hypertension was reduced by 65% at 1 year after surgery. (Ghiassi 2012)

  iii. In a US study, the average number of diabetic medications decreased from 2.2 to less than 1 within 2 weeks after surgery. (Slater 2011)

  iv. In a UK study, 37.5% of surgery-eligible patients stopped all glucose-lowering medication after bariatric surgery. (Johnston 2011)
• Bariatric surgery may lead to significant reductions in utilization of post-procedure health services due to improvement in patients’ metabolic disorders.

  i. In Brazil, absolute post-surgery cost savings were highest among obese patients with multiple comorbidities. (Sussenbach 2012)

  ii. One UK study noted a reduction in length of hospital stay by 52%, number of hospital admissions by 40.2 %, and regular medications by 26 %. (Karim 2013)

  iii. In the US, there was a 70.5% reduction in healthcare cost 3 years after surgery with RYGB, and a projected societal cost savings of $5 billion. (Ewing 2011)

  iv. In the US and UK, studies have reported cost savings of over 60% over 3 years after surgery as compared to standard of care. (Makary 2010)

• Indirect cost savings may also be realized due to increase in patients’ productivity and likelihood of working post-surgery, potentially leading to reduced use of state benefits.

  i. In patients undergoing bariatric surgery, a 32% increase in paid work and an increase in mean working hours by 19% have been reported. These patients also claimed state benefits at rates 3-4 times less than those observed before surgery. (Richards 2011)

  ii. One year after bariatric surgery, 24% of previously unemployed patients had achieved full time employment. (Turchiano 2011)

• The financial breakeven point for bariatric surgery is typically in the 2-7 years range

  i. In Mexico, the break-even point is 6.94 years in surgical patients without comorbidities. (Zanella 2011)

  ii. The break-even point in the Czech Republic for all surgery-eligible patients is 3 years. (Roubik 2012)

  iii. The break-even point in the US for all obese patients undergoing gastric banding is 4 years for (Finkelstein 2013)

  iv. A breakeven point of 5.25 years was reported for all surgery-eligible patients in the US undergoing gastric banding. (Finkelstein 2013)
v. Comorbidity resolution after bariatric surgery contributed to a break-even time of 2 years for patients undergoing laparoscopic surgery and 4 years for patients undergoing open surgery. (Richards 2011)

- Breakeven point is shorter for patients with BMI≥40 kg/m² and larger numbers of comorbidities.
  i. The break-even point for patients with type II diabetes in the UK was found to be 4.8 years when only considering glucose-lowering medications as the source of cost savings. (Johnston 2011)
  ii. In a US population of morbidly obese patients undergoing gastric bypass, the breakeven point was 3.5 years. (Mullen 2010)
  iii. In Mexico, the break-even point is 4.4 years in morbidly obese type-2 diabetic patients. (Zanella 2011)
  iv. In a population of patients undergoing gastric banding, the break-even point for patients with diabetes was just over 2 years. (Finkelstein 2013)
  v. A breakeven point of 1.25 years was reported for patients in the US with BMI>40 kg/m² and with concomitant T2DM. (Finkelstein 2013)
  vi. In a US database study combined with a literature review, total surgery costs were fully recovered by the payer after 3.9 years (47 months) for LRYGB. (Cremieux 2012)
• Any BMI between 35 and 40 is severe obesity*
• A BMI between 40 and 44.9 is morbid obesity
• A BMI of ≥45 is super obese

* In South Korea, severe obesity is defined as BMI≥30kg/m² (Song 2013)²

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**Definition of obesity per World Health Organization BMI Classification¹**

<table>
<thead>
<tr>
<th>BMI (kg/m²)</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 18.5</td>
<td>underweight</td>
</tr>
<tr>
<td>18.5–24.9</td>
<td>normal weight</td>
</tr>
<tr>
<td>25.0–29.9</td>
<td>overweight</td>
</tr>
<tr>
<td>30.0–34.9</td>
<td>class I obesity</td>
</tr>
<tr>
<td>35.0–39.9</td>
<td>class II obesity</td>
</tr>
<tr>
<td>≥ 40.0</td>
<td>class III obesity</td>
</tr>
</tbody>
</table>
“Recognizing obesity as a disease will help change the way the medical community tackles this complex issue.”
American Medical Association (AMA) board member Patrice Harris, M.D, in the 2013 AMA press release declaring obesity a disease

Obesity is prevalent worldwide

- In 2008, more than 1.4 billion adults, 20 and older, were overweight. Of these over 200 million men and nearly 300 million women were obese.  
- In 2008, 35% of adults aged 20 and over (worldwide) were overweight and 11% were obese.

Figure 1: AFR – Africa; AMR – Americas; EMR – Eastern Mediterranean; EUR – Europe; SEAR – South East Asia; WPR – Western Pacific

Figure 1: Global percent of population obese by region, gender, and income

% obese (BMI 30+), ages 20+, age std

% of population

AFR AMR EMR EUR SEAR WPR

Men Women Both Sexes

0 10 20 30 40 50 60 70
Obesity has serious health consequences

- The AMA recognized obesity as a disease in 2013, requiring a range of medical interventions to advance obesity treatment and prevention.³

- Many studies have shown that obesity is associated with increased mortality, decreased quality of life, increased disability and increased healthcare costs.⁴,⁵,⁶

- Being overweight (BMI>25kg/m²) or obese (BMI>30kg/m²) is the fifth leading risk for global deaths.²

- A systematic review and meta-analysis⁷ of 89 studies (90% from United States [US] and European Union [EU]) provides a comprehensive estimate of the incidence of 18 co-morbidities attributable to being overweight or obese. The incidence for T2DM, cardiovascular disease and cancer were particularly significant (See Table 1).

- Multiple studies have shown the risk of T2DM is significantly higher in the obese population than among those of normal weight. (Terranova 2012)⁷,⁸,⁹
Table 1
Relative comorbidity risks related to being overweight or obese and number of studies reviewed to determine them.

<table>
<thead>
<tr>
<th>Disease</th>
<th>Relative risk</th>
<th>95% CI</th>
<th>Studies included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 2 diabetes (female)</td>
<td>12.41</td>
<td>(9.03–17.06)</td>
<td>4</td>
</tr>
<tr>
<td>Type 2 diabetes (male)</td>
<td>6.74</td>
<td>(5.55–8.19)</td>
<td>4</td>
</tr>
<tr>
<td>Osteoarthritis (male)</td>
<td>4.20</td>
<td>(2.76–6.41)</td>
<td>2</td>
</tr>
<tr>
<td>Pulmonary embolism</td>
<td>3.51</td>
<td>(2.61–4.73)</td>
<td>1</td>
</tr>
<tr>
<td>Endometrial cancer</td>
<td>3.22</td>
<td>(2.91–3.56)</td>
<td>8</td>
</tr>
<tr>
<td>Coronary artery disease (female)</td>
<td>3.10</td>
<td>(2.81–3.43)</td>
<td>2</td>
</tr>
<tr>
<td>Chronic back pain</td>
<td>2.81</td>
<td>(2.27–3.48)</td>
<td>1</td>
</tr>
<tr>
<td>Kidney cancer (female)</td>
<td>2.64</td>
<td>(2.39–2.90)</td>
<td>4</td>
</tr>
<tr>
<td>Hypertension (female)</td>
<td>2.42</td>
<td>(1.59–3.67)</td>
<td>3</td>
</tr>
<tr>
<td>Gallbladder disease (female) &lt;sup&gt;a&lt;/sup&gt;</td>
<td>2.32</td>
<td>(1.17–4.57)</td>
<td>3</td>
</tr>
<tr>
<td>Pancreatic cancer (male)</td>
<td>2.29</td>
<td>(1.65–3.19)</td>
<td>4</td>
</tr>
<tr>
<td>Osteoarthritis (female) &lt;sup&gt;b&lt;/sup&gt;</td>
<td>1.96</td>
<td>(1.88–2.04)</td>
<td>2</td>
</tr>
<tr>
<td>Colorectal cancer (male)</td>
<td>1.95</td>
<td>(1.59–2.39)</td>
<td>7</td>
</tr>
<tr>
<td>Hypertension (male)</td>
<td>1.84</td>
<td>(1.51–2.24)</td>
<td>1</td>
</tr>
<tr>
<td>Kidney cancer (male)</td>
<td>1.82</td>
<td>(1.61–2.05)</td>
<td>4</td>
</tr>
<tr>
<td>Congestive heart failure (male) &lt;sup&gt;c&lt;/sup&gt;</td>
<td>1.79</td>
<td>(1.24–2.59)</td>
<td>1</td>
</tr>
<tr>
<td>Congestive heart failure (female) &lt;sup&gt;b&lt;/sup&gt;</td>
<td>1.78</td>
<td>(1.07–2.95)</td>
<td>3</td>
</tr>
<tr>
<td>Asthma (female) &lt;sup&gt;d&lt;/sup&gt;</td>
<td>1.78</td>
<td>(1.36–2.32)</td>
<td>4</td>
</tr>
<tr>
<td>Coronary artery disease (male) &lt;sup&gt;b&lt;/sup&gt;</td>
<td>1.72</td>
<td>(1.51–1.96)</td>
<td>5</td>
</tr>
<tr>
<td>Colorectal cancer (female)</td>
<td>1.66</td>
<td>(1.52–1.81)</td>
<td>8</td>
</tr>
<tr>
<td>Pancreatic cancer (female)</td>
<td>1.60</td>
<td>(1.17–2.20)</td>
<td>6</td>
</tr>
<tr>
<td>Stroke (male)</td>
<td>1.51</td>
<td>(1.33–1.72)</td>
<td>4</td>
</tr>
<tr>
<td>Stroke (female)</td>
<td>1.49</td>
<td>(1.27–1.74)</td>
<td>3</td>
</tr>
<tr>
<td>Asthma (male) &lt;sup&gt;d&lt;/sup&gt;</td>
<td>1.43</td>
<td>(1.14–1.79)</td>
<td>3</td>
</tr>
<tr>
<td>Gallbladder disease (male) &lt;sup&gt;e&lt;/sup&gt;</td>
<td>1.43</td>
<td>(1.04–1.96)</td>
<td>3</td>
</tr>
<tr>
<td>Ovarian cancer</td>
<td>1.28</td>
<td>(1.20–1.36)</td>
<td>8</td>
</tr>
<tr>
<td>Esophageal, &lt;sup&gt;ns&lt;/sup&gt;</td>
<td>1.20</td>
<td>(0.95–1.53)</td>
<td>1</td>
</tr>
<tr>
<td>Breast cancer (female)</td>
<td>1.13</td>
<td>(1.05–1.22)</td>
<td>10</td>
</tr>
<tr>
<td>Prostate cancer, &lt;sup&gt;ns&lt;/sup&gt;</td>
<td>1.05</td>
<td>(0.85–1.30)</td>
<td>7</td>
</tr>
</tbody>
</table>
Costs of obesity are increasing

- A systematic review for economic burden of obesity worldwide found that obese individuals have medical costs that were approximately 30% greater than their normal weight peers, based on 32 articles between 1990 and June 2009.\textsuperscript{10}

- According to World Health Organization (WHO) Europe, obesity is responsible for 2–8% of health costs and 10–13% of deaths in different parts of the region.\textsuperscript{11}

- A study based on data from the US Medical Expenditure Panel Survey (MEPS), found that obesity was responsible for about 6% of medical costs in 1998, or about $42 billion (in 2008 dollars). By 2006, obesity was responsible for closer to 10% of medical costs—nearly $86 billion a year.\textsuperscript{4}

- The US is expected to spend $344 billion on health care costs attributable to obesity in 2018 if rates continue to increase at their current levels.

- The cost of obesity can be evaluated through its direct and indirect effects on expenditure:

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**Figure 2**

Obesity’s direct and indirect effects on expenditure

Source: Ashrafian 2011
As defined by studies based in the UK, direct costs include disease prevention, assessment, diagnosis and treatment. These include the costs of treating co-morbidities such as diabetes, heart disease, hypertension, metabolic syndrome, sleep apnea, cancer and joint degeneration. (Picot 2012, Ashrafian 2011)

i. Obesity-related direct costs may account for 2-7% world healthcare expenditure. (Terranova 2012)

ii. Indirect costs attributed to obesity in the UK and EU include loss of work productivity caused by increased sick leave, absenteeism, long-term disability and overall reduction in productive work years due to shortened life expectancy. (Terranova 2012, Ashrafian 2011)

iii. A study in 2008 reviewed 31 articles and concluded that indirect costs worldwide ranged from $448.29 million ($204 per obese person) in Switzerland to $65.67 billion ($1627 per obese person) in the US.12

iv. Obesity is the source of a significant economic burden in most countries across the world.

Table 2
Direct and Indirect Costs of Obesity by Country

<table>
<thead>
<tr>
<th>Country</th>
<th>Direct Cost (year)</th>
<th>Indirect Cost (year)</th>
<th>% of Total Annual Spending</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>£4.2 billion (2007) 13</td>
<td>£15.8 billion (2007) 14</td>
<td>Obesity costs represented 4.6% of total NHS annual spending in 2002 15, 16</td>
</tr>
<tr>
<td>Canada</td>
<td>CDN $1.98 billion (2008) 16</td>
<td>CDN $2.63 billion (2008) 16</td>
<td>4.1% of the total healthcare costs in Canada in 2010 19</td>
</tr>
<tr>
<td>South Korea</td>
<td>1.8 billion (did not specify direct or indirect cost, 2011) 20</td>
<td></td>
<td>3.7% of healthcare costs in 2011 20</td>
</tr>
<tr>
<td>China</td>
<td>US $6 billion (2000) 21</td>
<td>US $43 billion (2000) 21</td>
<td>0.48% and 3.58% of the gross national product (GNP) of China for direct and indirect costs, respectively in 2000 21</td>
</tr>
<tr>
<td>Mexico</td>
<td>US $3.2 billion (did not specify direct or indirect cost, 2008) 22</td>
<td></td>
<td>13% of spending on health annually 22</td>
</tr>
</tbody>
</table>

Sources: Various – see above
CHAPTER 1.2

ECONOMIC BURDEN OF TYPE 2 DIABETES MELLITUS (T2DM)

Diabetes presents an increasing epidemiological and economic burden on national healthcare systems and economies worldwide. 23

- Diabetes Straining Healthcare Budgets
- Health Consequence and Resource Use Associated with T2DM

Diabetes is a worldwide epidemic.

- In 2012, there were an estimated 371 million people with diabetes (8.3% of the world’s population). T2DM accounts for 90% of diabetes cases globally. 24 By 2030, the prevalence is projected to rise to 552 million (8.9% of the world’s projected population).

Table 3
Regional Population Estimates for People with Diabetes – 2011 and 2030 25

<table>
<thead>
<tr>
<th>REGION</th>
<th>2011</th>
<th>2030</th>
<th>Increase in the no. of people with diabetes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Population</td>
<td>No. of people with diabetes</td>
<td>Comparative diabetes prevalence</td>
</tr>
<tr>
<td>AFR</td>
<td>387</td>
<td>14.7</td>
<td>4.5</td>
</tr>
<tr>
<td>EUR</td>
<td>653</td>
<td>52.8</td>
<td>6.7</td>
</tr>
<tr>
<td>MENA</td>
<td>356</td>
<td>32.6</td>
<td>11.0</td>
</tr>
<tr>
<td>NAC</td>
<td>322</td>
<td>37.7</td>
<td>10.7</td>
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<td>SACA</td>
<td>289</td>
<td>25.1</td>
<td>9.2</td>
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<td>856</td>
<td>71.4</td>
<td>9.2</td>
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<td>WP</td>
<td>1,544</td>
<td>131.9</td>
<td>8.3</td>
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<tr>
<td>World</td>
<td>4,407</td>
<td>366.2</td>
<td>8.5</td>
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</tbody>
</table>

- The top three countries with the most people with diabetes are China, India and the US.
• The prevalence of T2DM and pre-diabetes is rising rapidly globally and has acquired epidemic status, particularly in developing countries. The number of people suffering from diabetes is expected to almost double from 285 million globally in 2010 to 439 million by 2030. The highest growth rates (between 72%–98%) are expected in South Asia, China, the Middle East and Africa. India and China top the list of countries projected to have the most T2DM patients by 2030 (79–87 million in India and 42–63 million in China).
Diabetes is straining healthcare budgets.

- Healthcare expenditure attributable to diabetes accounted for 11.6% of global healthcare expenditure in 2010, and this is projected to increase by 30–34% by 2030. This is rate is higher than predicted global population growth among individuals aged 20–79 during the same time period.\textsuperscript{28}

- Diabetes-related expenditure is expected to grow more rapidly than population growth because diabetes prevalence is impacted by the aging population in developed markets and increased urbanization in developing markets.\textsuperscript{28}

- Disparities exist in healthcare expenditure for diabetes between regions. Figure 4 below compares the health expenditure in the 25 countries with the largest population of people with diabetes. A large majority of people living with diabetes reside in low and middle-income countries, where they receive less than 20% of global spending for diabetes.\textsuperscript{28}

- The lifetime direct medical cost of treating T2DM and associated diabetic complications varies between US $54,700 and $124,700 for men and between US $56,600 and $130,800 in women in the US (2013 estimates).\textsuperscript{29} A 2007 study estimated that the total cost associated with T2DM in the US was $159.5 billion.\textsuperscript{30}
**Figure 4**
Annual health expenditure for diabetes vs persons with diabetes in the 25 countries with the largest numbers of persons with diabetes in 2010

*ID: International Dollars*
Diabetes is associated with serious health consequences and expanded use of healthcare resources.

- Diabetes is associated with serious complications including coronary heart disease, stroke, kidney failure, neuropathy, blindness, leg and foot amputations, and pregnancy complications. People with diabetes, 90% of whom have T2DM, have 2–4 times as many physician visits and longer lengths of hospital stays compared to individuals without diabetes.

- They incur medical costs that are 2–3 times higher than those without diabetes.

- Macrovascular complications are a major consequence of T2DM and account for the highest cost of managing T2DM patients. For example, a study on the South Korean population showed that the annual direct medical costs for a patient with only macrovascular, only microvascular, or both macro- and microvascular complications were respectively 2.7, 1.5 and 2.0 times higher than the costs for T2DM patients without complications.

Table 5
Direct and indirect costs of diabetes in the UK, US, South Korea, Mexico, China and India

<table>
<thead>
<tr>
<th>Country</th>
<th>Direct Cost (year)</th>
<th>Indirect Cost (year)</th>
<th>% of Total Annual Spending</th>
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<tbody>
<tr>
<td>UK</td>
<td>£8.8 billion (2010/11)</td>
<td>£13.0 billion (2010/11)</td>
<td>10% of total NHS expenditures</td>
</tr>
<tr>
<td>US</td>
<td>USD $105.7 billion (2007)</td>
<td>USD $53.8 billion (2007)</td>
<td>14% of the North America and Caribbean Region national health expenditure in 2010</td>
</tr>
<tr>
<td>South Korea</td>
<td>USD 1,939 per patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mexico</td>
<td>$1.164 billion (2005)</td>
<td>$177 million (2005)</td>
<td>7% of Mexico’s national health expenditure (2005)</td>
</tr>
<tr>
<td>India</td>
<td>$26.7 billion (2010)</td>
<td>$5.2 billion (2010)</td>
<td></td>
</tr>
</tbody>
</table>

Sources: Various – see above
CHAPTER 1.3

CLINICAL GUIDELINES AND HTA REQUIREMENTS: CONSENSUS AND COMPARISONS

“Bariatric and metabolic surgery procedures are indicated for patients with clinically severe obesity. Currently, these procedures are the most successful and durable treatment for obesity.”

–American Association of Clinical Endocrinologists (AACE)/ The Obesity Society (TOS)/ American Association of Metabolic and Bariatric and metabolic surgery (ASMBS) 2013.37

HTA Methodology

Initial Search (n=24)

• 9 countries with key mature healthcare markets that are known to publish HTA reports (US, Canada, countries in the EU, Australia) as well as Latin American countries to be globally representative
• Search of HTAWatch database for bariatric and metabolic surgery, procedure, and obesity terms
• Latin America only: Search of ISPOR.org for names of HTA bodies and review of their publications for mentions of bariatric and metabolic surgery

Inclusion and Exclusion Criteria (n=23)

Inclusion:
• Reviews evaluating either a specific bariatric and metabolic surgery procedure or the entire category of bariatric and metabolic surgery for clinical and/or cost-effectiveness for the treatment of obesity and its comorbidities
• No timeframe restrictions were applied (including retroactive timeframes)

Exclusion:
• Only HTAs available in English were included in the analysis

Health Technology Assessments (n=23)

• Articles are grouped and analyzed by region, study methodology, and topic of focus (e.g. bariatric)
Bariatric and metabolic surgery is recommended as a later line of treatment for obesity in patients with BMI >40kg/m² and for those with BMI in the 35–40kg/m² range with one or more weight-related comorbidities. Recent guidelines in Asia and the US include recommendations for lower BMI ranges. RYGB is acknowledged by most HTAs as the most efficacious surgery in terms of weight loss and comorbidity resolution.

- Bariatric and metabolic surgery is recommended for weight loss and addressing certain weight-related comorbidities by most HTAs and clinical guidelines for treating obesity around the world. Weight related co-morbidities include hypertension, diabetes, heart failure, and sleep apnea. (Brats 2005, IECS 2005, Medical Advisory Secretariat 2005, Bockelbrink 2008, Colquitt 2009, Medical Advisory Secretariat 2009b, Medical Advisory Secretariat 2009c, Klarenbach 2010, Segal 2010, Tice 2012, NHS QIS 2010)

Figure 5
Evolution of clinical guidelines for bariatric and metabolic surgery

Except in Asia and more recently in the US, Bariatric Surgery is advocated as a later line of treatment (e.g. 3rd line) in patients with BMI >40kg/m² and for those with BMI in the 35-40kg/m² range with one or more weight-related comorbidities (e.g., hypertension, diabetes, heart failure, or sleep apnea)
• In the US, BCBS TEC and the Agency for Healthcare Research and Quality (AHRQ) have explored the use of bariatric and metabolic surgery in patients with BMI < 35kg/m², especially among those with T2DM. A growing consensus among US organizations such as NIH and AACE/TOS/ASMBS (as well as Cochrane) support the intervention’s benefits in populations with BMI < 35kg/m² and comorbidities (Colquitt 2009). However, the surgery is generally not recommended at this BMI range in the US, largely due to lack of long-term clinical effectiveness data (BCBSTEC 2012a, BCBSTEC 2012b, Maggard-Gibbons 2013, Asian Diabetic Surgery Summit [ADSS] 2002).

i. A set of guidelines in Taiwan recommended even lower BMI thresholds for bariatric and metabolic surgery (for patients with BMI > 32.5 kg/m² with comorbidities or for patients with BMI > 37.5kg/m²) due to population-specific considerations.

ii. More recently, BMI thresholds in certain guidelines in the Asia-Pacific region have been further reduced to include patients with BMI > 27.5kg/m².

• HTA agencies and other technology reviewers consider RYGB to be the most efficacious form of bariatric and metabolic surgery as demonstrated by its sustained weight loss at least two years after surgery and higher rates of diabetes resolution, though they do note...
that RYGB has a relatively higher rate of adverse events compared with LAGB and SG.\textsuperscript{42, 45} (Medical Advisory Secretariat 2005, Medical Advisory Secretariat 2009b, Tice 2009, Habermann 2012)

- HTA reviewers have noted continuing decreases in adverse event rates as safer LRYGB continues to replace higher-risk open bypass. (Habermann 2012)

**Bariatric and metabolic surgery may reduce healthcare costs post-surgery through lower resource utilization**

- An evaluation of US private payer claims data by AHRQ found that at 12 months post-surgery, medication usage for obesity-related diabetes, hypertension, and hyperlipidemia fell by more than half. (Segal 2010) Similar cost savings were also observed in Canada. (Tice 2012, CADTH 2013)

- Economic evaluations by HTA agencies around the world have established the cost-effectiveness of bariatric and metabolic surgery, showing it to be superior to other methods of weight and metabolic control. (IECS 2005, Medical Advisory Secretariat 2005, Bockelbrink 2008, Medical Advisory Secretariat 2009c, Klarenbach 2010, CADTH 2013, NHS QIS 2010, NHS QIS 2012)

- In Canada, bariatric and metabolic surgery (specifically RYGB) was found to be net cost saving compared to the standard of care of diet, exercise, and pharmaceutical therapy over the course of a patient’s lifetime. (CADTH 2013)

**Preferences vary regarding operations in high-volume hospitals and centers of excellence**

- Generally, guidelines around the world recommend bariatric and metabolic surgery procedures are performed at high volume centers with deep multi-disciplinary expertise.\textsuperscript{14, 39, 44, 46, 47, 48}

- However, the US Centers for Medicare & Medicaid Services (CMS) recently made a decision in disagreement with this consensus; on September 24, 2013 the CMS announced it dropped its requirement for performing bariatric and metabolic surgery at centers of excellence as a condition of reimbursement.\textsuperscript{49}
Data gaps include head-to-head comparisons and long-term outcomes

- Organizations around the world such as American Gastroenterological Association (AGA), Cochrane, the French National Authority for Health (HAS), the NHS, the UK’s National Institute for Health and Care Excellence (NICE), and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) have acknowledged the need for direct head-to-head trials between RYGB, LAGB, and SG.\(^{14, 42, 46, 53}\) (Colquitt 2009, NHS QIS 2012)

- These organizations have also noted that studies examining the long-term impact of bariatric and metabolic surgery on weight loss and comorbidity resolution remain inconclusive, requiring further studies.\(^{42}\) (BCBSTEC 2012b, NHS QIS 2010)

Examples of coverage gaps persist worldwide despite support from professional guidelines and HTA recommendations

- Although both HTAs and professional guidelines support that bariatric and metabolic surgery is the only weight loss approach which results in sustained long-term weight loss, coverage limitations remain for bariatric and metabolic surgery around the world.

- Coverage requirements in the UK, US, and Germany place bariatric and metabolic surgery as a later-line treatment, requiring prior failure on another weight loss program before surgery is covered.\(^{14, 49, 50, 51, 52}\)

- Coverage for comparatively newer procedures such as SG in the US and AGB in some Canadian provinces lag behind HTA and professional guideline recommendations.\(^{39, 51}\)

- In France, some post-operative nutritional supplements and follow-up operations are explicitly noted as not covered.\(^{53}\)

- In some countries such as Taiwan, access to bariatric and metabolic surgery may be limited due to relatively low procedure volumes as well as the limited availability of qualified surgeons in the country. (Buchwald 2013)
1.4

BIBLIOGRAPHY:

SECTION 1


CHAPTER 2
Growing Evidence: Is Bariatric Surgery Cost Saving?
CHAPTER 2.1

METHODOLOGY–SYSTEMATIC LITERATURE REVIEW

The economic effectiveness and impact of bariatric and metabolic surgery were systematically reviewed. Reviewers screened titles and abstracts of citations from Ovid MEDLINE and PubMed published between 2010 to March 2014, and applied inclusion criteria (Box A) to the full text of potentially relevant articles using a standardized form. Data were extracted by a reviewer using a standardized form.

Box A: Inclusion criteria for systematic review

- Patients: People who underwent bariatric and metabolic surgery of varying demographics (including various BMI ranges)
- Interventions: Open and laparoscopic bariatric and metabolic surgical procedures.
- Comparators/Intervention:
  - i. Bariatric and metabolic surgery procedures compared against other bariatric and metabolic surgery procedures
  - ii. Bariatric and metabolic surgery procedures compared against nonsurgical interventions
  - iii. Economic/effectiveness impact before and after surgery, or
  - iv. Coverage policy change: implementation of the Center of Excellence (COE).
- Outcomes: Studies must have reported on or discussed at least one of the following economic related outcomes:
  - i. Quality of life
  - ii. Cost-effectiveness ratio
  - iii. Cost impact
  - iv. Return on investment, or
  - v. Change in obesity related co-morbidities and its related costs.
- Study Design: Randomized trails, observational studies and review articles.
- Other criteria considerations: Abstracts or conference presentations were eligible if sufficient details were presented to allow an appraisal of the methodology and results.
- There was no language restriction.
2.1 CHAPTER

Initial Literature Search (n=288)
- Databases: Ovid MEDLINE and PubMed
- Search terms: obesity, bariatric and metabolic surgery terms, cost/economic terms
- Search period: January 2010 to March 2014

Exclusion criteria:
- Does not meet study inclusion criteria (Box A)
- Wrong study focus, e.g., non-adult studies
- Non-human subjects
- Duplicates
- Abstracts only without clear methodology
- Irrelevant outcomes, e.g., wrong procedure focus
- Studies assessed as partially applicable with very serious limitations
- Studies in which it was unclear whether patient T2DM was early onset

Title and Abstract Review (n=288)
- Wrong study focus, e.g., non-adult studies
- Duplicates (for the same study with poster presentation followed by a full article publication, only the full article is included)
- Irrelevant outcomes, e.g., wrong procedure focus

Exclusion criteria:
- Wrong study focus, e.g., non-adult studies
- Duplicates (for the same study with poster presentation followed by a full article publication, only the full article is included)
- Irrelevant outcomes, e.g., wrong procedure focus

Full Article Review (n=121)
- Articles are grouped and analyzed by regions, study methodologies and focused topics

Bariatric and metabolic surgery HEOR articles (n=104)
## Regional Snapshot

<table>
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<tr>
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<td>EMEA (3)</td>
<td>LA (2)</td>
<td>NA (7)</td>
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- **EMEA**: 6
- **LA**: 3
- **NA**: 11

### ROI (11)

- **APAC**: 0
- **EMEA**: 2
- **LA**: 2
- **NA**: 7

### Review (4)

- **APAC**: 0
- **EMEA**: 2
- **LA**: 0
- **NA**: 2

### Access, Coverage and COE (23)

- **APAC**: 1
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- **LA**: 1
- **NA**: 14

### Global (1)

### Access and Coverage (27)

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### Review (4)

- **APAC**: 0
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- **NA**: 3
As previously noted, the treatment of obesity, its related complications and co-morbid risks can have a significant burden on the healthcare system of a region, both administratively and financially. For many obese patients and their physicians, the standard of care (diet, exercise, and pharmaceutical therapy) is often the treatment of first choice; however, lack of long-term success has made surgery increasingly the only successful long-term option left for many morbidly obese patients.

But how cost-effective is surgery as an option for treatment, and do the long-term benefits outweigh the upfront cost? Evidence across the globe is increasingly demonstrating a surgical approach to be cost-effective over the nonsurgical standard of care.

Systematic Review: Economic Comparative Research Of Bariatric And Metabolic Operations Including Cost-Effectiveness And Cost Benefit Studies
The systematic review found 40 articles that described cost-effectiveness or cost benefit analyses, including 18 cost-effectiveness studies, 12 other studies of comparative economic value, and 10 review studies. Geographically, 20 studies were conducted in North America, 15 in Europe, 3 in Latin America, and 2 in the Asia/Pacific region.

Overall, bariatric and metabolic surgery appears to have a positive economic impact in the management of obesity as opposed to nonsurgical interventions in terms of: reduced medication costs and frequency of hospital visits, as well as long-term reduction in system healthcare costs. (Dumon 2011)

**CEA studies across the globe have largely demonstrated favorable results supporting a surgical approach to obesity as cost-effective compared to nonsurgical strategies, especially in patients with morbid obesity or with obesity related comorbidities.**


- For patients with BMI>40kg/m², data supports that the surgical approach to treatment of obesity is cost-effective or dominant over nonsurgical treatment strategy. (Tice 2009, BCBSTEC 2012b)


- Outcomes and benefits from improving outcomes via surgical management are due to weight loss, improvement of obesity-associated comorbidities, longevity and quality of life.
Surgery is cost-effective in treating type 2 diabetes mellitus (T2DM) patients with BMI>35 kg/m²

- In patients with T2DM patients and BMI>35kg/m², surgical treatment has shown to be cost-effective versus nonsurgical treatment. (Picot 2012, Banka 2012, Chang 2011, Hashemi 2010, Hoerger 2010, Faria 2013, Pollock 2013, Nasciben 2010_2).

- In the US, overall, laparoscopic roux-en-y gastric bypass (RYGB) and laparoscopic adjustable gastric banding (LAGB) appear to be relatively cost-effective treatments in the severely obese diabetic population, with cost-effectiveness ratios ranging from $7,000 to $13,000/QALY. These cost-effectiveness ratios are lower than the cost-effectiveness ratios for commonly applied diabetes interventions. Moreover, they are well below the $50,000/ QALY benchmark sometimes applied as a measure of society’s willingness to pay for health interventions. (Heorger 2010)

- CADTH reported the cost per QALY for RYGB compared to nonsurgical interventions for obesity to be cost-saving in Canada for obese patients with T2DM. (CADTH 2013) This has been confirmed by other Canadian economic modeling studies. (Klarenbach 2010, Hashemi 2010)

Studies found similar levels of cost-effectiveness at lower BMIs.

- One study looking at patients with BMI 30–40kg/m² in South Korea (in South Korea, severe obesity is defined as BMI≥30kg/m²) concluded that bariatric and metabolic surgery was a cost-effective alternative to nonsurgical interventions over a lifetime, providing substantial lifetime benefits for severely obese Korean patients. (Song 2013)

- An additional study in South Korea found surgery to be cost-effective for treating patients with BMI >30kg/m² with diabetes. (Song 2012)
Bariatric and metabolic surgery demonstrated cost-effectiveness compared to nonsurgical obesity treatment in all countries where it has been evaluated. It has also been associated with net cost savings in more than half of countries in which cost savings were evaluated.

- Positive cost-savings were observed when comparing the costs of surgery to nonsurgical treatment.
  
  i. Most economic comparative studies have shown cost savings in overall healthcare expenditures and/or resources used as compared with nonsurgical treatment. (Gripeteg 2012, Lao 2012, Hayashi 2011, Nasciben 2010_1, Leva 2013, Finkelstein 2013)

- Studies in Austria, Canada, France, Germany, Italy, and Portugal have shown bariatric and metabolic surgery leads to net cost savings paired with improved clinical outcomes such as weight loss and resolution of comorbidities when compared with nonsurgical interventions. (Maklin 2011, Hashemi 2010 poster, Faria 2013, Terranova 2012) Additionally, results from a Finnish study showed that bariatric and metabolic surgery was less costly and more clinically effective in comparison to the standard of care. Over 10 years, costs were about 1.5 times lower with bariatric and metabolic surgery compared to conventional treatment. (Maklin 2011)

- In other countries such as Australia, Brazil, Spain, the UK, and the US, bariatric and metabolic surgery was found to be cost-effective compared to standard of care, with incremental cost-effectiveness ratios (ICERs) comfortably below common cost-effectiveness thresholds such as US $50,000/QALY or local equivalents. (Picot 2012, Banka 2012 poster, Chang 2011, Hoerger 2010, Pollock 2013, Nasciben 2010_2 poster, Terranova 2012)
Figure 7
Comparison of Bariatric and Metabolic Surgery with Nonsurgical Interventions for Obesity in Terms of Cost-Effectiveness and Cost Savings


Fig.7: In all countries where it has been evaluated, bariatric and metabolic surgery has demonstrated greater effectiveness than nonsurgical treatment for the management of obesity. Surgical intervention has also been associated with net cost savings compared to nonsurgical standard of obesity care in more than half of countries in which cost savings were evaluated.

- Some studies, however, have indicated that bariatric and metabolic surgery does not appear to reduce healthcare expenditure as compared to nonsurgical treatment. (Neovius 2012, Maciejewski 2012, Mundbjerg 2013, Weiner 2013). Possible reasons for deviations include overall costs relative to costs detail where we start to see savings, and older open procedures that are less safe and less effective compared to more recently developed laparoscopic approaches.

  i. A study based on administrative data from US Department of Veterans Affairs (VA) medical centers concluded that bariatric and metabolic surgery does not appear to be associated with reduced health care expenditures 3 years after the procedure in a cohort of predominantly older men. (Maciejewski 2012)
ii. A second study concluded that surgically treated patients used more inpatient and nonprimary outpatient care during the first 6-year period after undergoing bariatric and metabolic surgery than patients who underwent nonsurgical treatment for obesity, though this was not the case at greater than 6 years. Drug costs from years 7 through 20 following intervention were lower for surgery patients than for control patients. (Neovius 2012)

iii. An additional US study concluded that bariatric and metabolic surgery does not reduce overall health care costs in the long term and pointed out that further studies are needed to assess the value of bariatric and metabolic surgery (Weiner 2013).

Major clinical endpoints incorporated in these economic analyses included weight loss and resolution of comorbidities such as T2DM. These improvements were associated with cost offsets such as reductions in medication use, hospital visits, and utilization of emergency services, while also extending life span and improving quality of life. Surgical complications also factored into the calculations.

Studies have found that the success rate (efficacy or complication rate) of bariatric and metabolic surgery depends on the expertise of the operating surgeon as well as other variables [2.5.11, 13, 15], and generalizability of results is problematic between countries with different medical care levels. (Afoke 2013, Khan 2013, Nguyen 2013_1)
CHAPTER 2.4

OTHER ECONOMIC STUDIES

Bariatric and metabolic surgery results in reduction of both direct and indirect costs of obesity and its comorbidities compared with standard of care for obesity, resulting in cost savings for the health system.

Systematic review: Economic research on bariatric and metabolic operations including budget impact analysis and return-on-investment

<table>
<thead>
<tr>
<th>Budget Impact Analysis and Return on Investment (37)</th>
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<tbody>
<tr>
<td>BIM and WTP (22)</td>
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<tr>
<td>ROI (11)</td>
</tr>
<tr>
<td>Review (4)</td>
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</tbody>
</table>

The results from the systematic review identified 37 articles that described economic benefits of bariatric and metabolic surgery, including 22 that reported budget impact and cost savings, 11 others that reported return on investment (ROI) and 4 overall review articles. Geographically, 20 articles consisted of analyses conducted in North America, 10 in Europe, 5 Latin America, and 2 in the Asia/Pacific region.

The analysis supports that bariatric and metabolic surgery results in cost savings over nonsurgical options, largely due to reduction in both direct costs such as reduced health examination, medication, professional care, and hospital stay, as well as indirect costs such as increases in patients’ work productivity post-surgery. The break-even point for bariatric and metabolic surgery is in the 2-7 year range, and was dramatically reduced for patients with BMI>40kg/m², especially...
2.4

for those with concomitant T2DM (the break-even point may be in the 1.25-5 year range for this population).

**Direct cost savings may be realized from reduced diabetes, asthma, and sleep apnea medication costs, reduced incidence of diabetes complications, and fewer healthcare professional contacts, among other factors.**

- Across 4 European countries, bariatric and metabolic surgery was found to be more cost saving over a 5-year period than standard medical management of diabetes (diet, exercise and pharmaceutical therapy). (Figure 8) (Terranova 2012)

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**Figure 8**

Cost Savings (USD) Per Diabetic Patient of LAGB and RYGB over SMM

![Cost Savings Chart](chart.png)

Source: Terranova 2012
SMM= Standard Medical Management

Fig. 8: While both LAGB and RYGB save costs relative to standard medical management of metabolic disorders, over a 5-year period, RYGB appears to be more cost saving than LAGB which may be associated with rebound weight gain after initial post-surgery weight loss.

- Across the globe, pharmaceutical utilization rates have declined following bariatric and metabolic surgery, especially for diabetes and cardiovascular medications in the first year following surgery.

  i. In a study conducted in the UK, (Johnston 2011) 37.5 % of patients stopped all glucose-lowering medication post-surgery.

  ii. In a US study of the VA population, the average number of diabetic medications decreased from 2.2 to <1 within 2 weeks after surgery, corresponding to a progressive diabetes medication cost savings by between 80% to 99.7% at 12 months after sleeve gastrectomy. (Slater 2011)
iii. A separate study of VA populations observed a cost savings of 88% for diabetes medications at 12 months after gastric bypass. Additionally, at 1 year after surgery, there was a reduction in annual cost of hypertension medications of 65%. (Ghiassi 2012)

iv. In Sweden, the average drug cost per patient at 7-20 years following intervention was $930 with bariatric and metabolic surgery as opposed to $1,123 with standard medical management for comorbidities (including several comorbidities such as: diabetes, gastrointestinal disorders, anemia and vitamin deficiency, cardiovascular disease, psychiatric disorders, and antiasthmatics), a reduction of 17%. (Neovius 2012)

v. Similar levels of cost savings were reported in Brazil for obese patients with comorbidities, even though the cost of bariatric and metabolic surgery appeared to increase by 10% from 2004 to 2007. (Salgado 2010)

vi. Post-surgery, percentage cost savings for both pharmaceutical treatment and hospital resources over 3 years in Brazil appeared to be highest for obese patients with a single comorbidity, as illustrated in Figure 9. (Sussenbach 2012)

Figure 9
Change in Cost of Treatment over Time with Bariatric and Metabolic Surgery, With One, Two or No Obesity Comorbidities Present

Source: Sussenbach 2012

Fig. 9: Change in Cost of Treatment (in Brazil (US dollar [USD] Equivalent). Over a span of 3 years, cost savings on a percentage basis in Brazil appeared to be highest for obese patients with a single comorbidity, while patients with 2 comorbidities experienced the greatest cost savings.
• Bariatric and metabolic surgery may lead to significant reductions in utilization of post-procedure health services due to improvement in patients’ metabolic disorders
  
  i. One UK study noted that for morbidly obese patients, compared to pre-surgery, length of hospital stay by was reduced by 52%, number of hospital admissions were reduced by 40.2%, and need for regular medications dropped by 26% post-surgery. (Karim 2013_2)
  
  ii. In the US, there was a 70.5% reduction in healthcare costs 3 years after surgery with RYGB [2.4:14]. Specifically in just the south plains region of Texas, bariatric and metabolic surgery is estimated to save $5 billion USD in post-procedure health services over 10 years. (Ewing 2011)

• Overall, bariatric and metabolic surgery may reduce cost of examination, medication, professional care, and metabolic disorders relative to the cost of standard health services
  
  i. In the US and UK, studies have reported greater than 60% cost savings for patients with obesity who underwent surgery compared with patients who received standard of care. (Makary 2010, Karim 2013_2, Perryman 2010)
  
  ii. In Brazil, total costs of medications and examinations due to RYGB decrease progressively with years following the surgery (Sussenbach 2012), as shown in Figure 9.
  
  iii. In Scotland, between 2008 and 2011, a total annual savings of £30,404 were realized. (Karim 2013_1)
  
  iv. In Spain, throughout the entirety of the clinical pathway for surgery, hospitalization complication rates were reduced by 25% and admission costs were reduced by 14%. Vidal 2012
A study sponsored by the National Institute of Allergy and Infectious Diseases reported that bariatric and metabolic surgery increased cost per patient pre- and post- surgery by over $24,000 over 6 years. (Bleich 2012) However, the study was limited to a subset of patients with private insurance, making it challenging to generalize these results to publicly-funded healthcare systems both in the US and for the rest of the world. Further, a report in Sweden noted that in patients aged 37-60 and with BMIs >34kg/m² (men) and 38kg/m² (women), bariatric and metabolic surgery increased the total number of days spent in the hospital by 35% over 20 years. Bariatric and metabolic surgery appeared to provide greater health benefits over 20 years, but at a higher cost than standard of care for obesity. (Neovius 2012)

Notwithstanding notable economic benefits of bariatric and metabolic surgery, establishing its long-term effects may be confounded by variability in expenses among institutions and populations as well as services and capital management. Importantly, since the non-adherence rate to follow-up visits after bariatric and metabolic surgery has been reported to be as high as 17.5%, a substantial number of patients undergoing bariatric and metabolic surgery are lost to follow-up leading to uncertainty about data on population-wide benefits of the intervention. (Maciejewski 2012)
Indirect cost savings may also be realized due to increases in patients’ work productivity post-surgery, increased paid work, potentially leading to reduced rates in claim of government benefits.

- In the UK, patients who have undergone bariatric and metabolic surgery and been assessed for changes in work, a 32% increase in paid work and a 19% increase in mean working hours have been reported. These patients also claimed state benefits at a rate of 3–4 times less than pre-surgery. (Richards 2011)

- In the US, one year after bariatric and metabolic surgery, 24% of the previously unemployed patients had acquired full time employment. (Turchiano 2011)

Time to break-even following bariatric and metabolic surgery is typically in the 2–7 year range, and is shorter for patients with T2DM and BMI>40kg/m^2, who typically reach break-even in the 1.25–5 year range.

- A break-even point of 1.25 years was reported for patients in the US with BMI>40kg/m^2 and with concomitant T2DM (Finkelstein 2013)

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**Figure 11**

Years Until Break-Even with Bariatric and Metabolic Surgery, by Presence of T2DM and by Country


Fig. 11: While time to recoup cost of bariatric and metabolic surgery is at most 7 years in obese patients, among those with T2DM, the break even time may be as short as 2 years.
• In the US, a study found that for patients in the 18–65 age group with BMIs of >35kg/m², the cost of laparoscopic bariatric surgery was fully recovered after 2.2 years. (Klein 2011)

• A UK study noted patients with preoperative glucose lowering medication costs of >1,000 pounds per patient per year, the cost of bariatric and metabolic surgery may be recouped in 4.8 years. (Johnston 2011)

• A similar break-even point was noted in a Swedish study. (Borg 2012)

• For the entire US healthcare system, one study found that by the second year, bariatric and metabolic surgery patients incurred fewer costs than the obese health plan population. (Mullen 2010)

• An economic simulation in the Mexican setting found a break-even point at 6.94 years. (Zanela 2012)

• One of the lowest break-even points was reported among private insurers in the US at 2.2 years and for morbidly obese patients at 1.5 years. The highest ROI was observed with LAGB with a break-even point (1.5 years) at half that of LRYGB (2.25 years). (Finkelstein 2013) These ROIs were observed from payer, societal, and employer perspectives.

Figure 12
Years Until Break-Even with Bariatric and Metabolic Surgery by BMI and by Procedure

Source: (Mullen 2010, Myers 2012, Finkelstein 2013, Dumon 2011)

Fig. 12: In the US, LAGB has a shorter break-even point than RYGB. Regardless of the specific procedure, break-even point improves with increasing BMI, and is especially superior for management of morbidly obese patients with diabetes where the break-even point is <2 years.
The following costs were typically assessed in computing ROI:

<table>
<thead>
<tr>
<th>Healthcare Utilization/Medical Costs</th>
<th>Pharmacy Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-patient/ out-patient/Office visit</td>
<td>Weight loss medications</td>
</tr>
<tr>
<td>Laboratory/Pathology</td>
<td>Anti-diabetic medications</td>
</tr>
<tr>
<td>Physical and occupational therapy</td>
<td>Anti-hypertensive medications</td>
</tr>
<tr>
<td>Sleep facilities</td>
<td>Dyslipidemic medications</td>
</tr>
<tr>
<td>ER visit</td>
<td>Psychotherapeutic agents</td>
</tr>
</tbody>
</table>

Systematic review of coverage policies, patient access to bariatric and metabolic surgery and willingness to pay

The systematic review identified 27 articles that described patient access and coverage policies. Geographically, 17 of those were conducted in North America, 7 in Europe, 1 Latin America, 1 in the Asia/Pacific region, and 1 global.

Notwithstanding potential economic benefits of bariatric and metabolic surgery intervention, patient access to the procedure remains a significant barrier to the treatment option realizing its full potential. Patient access may be limited and shaped by many factors, including hospital resources, coverage policies, physician expertise and adoption, and patient preference and socioeconomic status.
Access to more qualified surgeons and accredited hospitals seem to improve surgical outcomes such as mortality, reoperations, complications, and readmissions.

- In reports from Taiwan and the US, high-volume hospitals touted lower length of stay, cost, and in-hospital mortality than their lower-volume counterparts. (Chiu 2012, Torrente 2013)

- Specifically, procedures conducted at centers of excellence (COEs) in the US resulted in reduction of reoperations by 0.3 %, complications by approximately 9%, and shorter lengths of stay by 0.3 days. (Nguyen 2012)

- However, a US study conducted following the Center for Medicare and Medicaid Studies (CMS)’s decision to restrict reimbursement of bariatric and metabolic surgery to COEs found no significant differences between COE and non-COE hospitals in terms of complications and reoperations. (Dimick 2013)

- Facilities specially designed for bariatric and metabolic surgery may incur 250% higher costs over standard care facilities.¹
  
i. For safe patient handing, the American Nurse Association recommends treatment sites be equipped with bariatric beds, total lift systems, wheelchairs in varying widths and depths, stretchers with a 1,000 pound capacity, 42-inch toilets and scales that are wheelchair accessible.²

There appear to be worldwide inequities in access to bariatric and metabolic surgery, as the population who actually receives bariatric and metabolic surgery may not reflect the individuals who need it the most.

- In Canada, socioeconomic factors play a major role in determining who does and does not undergo bariatric and metabolic surgery despite medical eligibility, with higher earning patients more willing to pay for faster access. (Gill 2014)

- By contrast, in the US, most patients who are eligible for bariatric and metabolic surgery have family incomes with 15% below poverty level. Furthermore, most surgically eligible patients tend to be less educated, and have less access to healthcare; more than one third (35%) of bariatric eligible patients being either uninsured or underinsured. (Sudan 2014)
• In publicly-funded healthcare systems such as Canada, waitlist prioritization and associated patient inconvenience appear to be a significant barrier to access. (Christou 2011) The waiting period was described as stressful, anxiety-provoking, and frustrating. However, for a higher cost of access (average of 2013 Canadian dollar [CAD] $17,000 per operation), wealthier patients can access private clinics with shorter wait times than public clinics. (Gregory 2013)

**However, in some areas, coverage of bariatric and metabolic surgery is increasing in populations with high levels of obesity-related comorbidities:**

• The chief health technology assessment agency in California has recommended that the state cover bariatric and metabolic surgery in patients with T2DM. (Tice 2012)

• HTAs linked to private payers in the US are also increasingly receptive to recommending coverage of bariatric and metabolic surgery in patients with obesity-related comorbidities, though coverage is not yet universal. (BCBSTEC 2012a, BCBSTEC 2012b)

**Patients’ willingness to pay depends on clinical severity and functional impairments related to obesity as well as on individual preferences.**

• In Brazil, sleep apnea appears to be the highest prioritization indicator that prompts patients to undergo bariatric and metabolic surgery. (Khawali 2011).

• In the Canadian setting, willingness to pay is notably contingent on income level, with higher earning patients (>CAN $80,000) likely to be the first to adopt bariatric and metabolic surgery. (Gill 2014)

• A study in Northern Ireland suggested bariatric and metabolic surgery may be preferred by younger females compared to males despite a similar prevalence of obesity. (Patterson 2014)
Example Coverage Policies and Restrictions:

- US: CMS covers bariatric and metabolic surgery for Medicare beneficiaries who are morbidly obese and have comorbid conditions. Bariatric and metabolic surgery is covered under Medicaid in 45 states. Some private insurers also cover bariatric and metabolic surgery on a limited basis, although individual plans have discretion over whether or not bariatric and metabolic surgery is covered. (Lee 2010)

  i. National coverage of LAGB appeared to incentivize higher use of that procedure, leading to decreased mortality, readmissions, length of stay, and reoperation. [2.5:4, 2.5:8]

  ii. Laparoscopic sleeve gastrectomy (LSG) is covered by all national plans in the US and grew faster in popularity in recent years than RYGB and LAGB. (Lee 2010, Lee 2010, Lee 2010)

  iii. Some payers require previous attempts at weight loss before covering bariatric and metabolic surgery sometimes requiring six months to one year of unsuccessful weight loss program participation. (Lee 2010, Lee 2010, Lee 2010)

- Brazil: Despite the large increase in the prevalence of obesity in Brazil, there is only one reference center for bariatric and metabolic surgery for every four million inhabitants, leading to long waiting lists. (Kelles 2011)

- Canada: Only RYGB is publically insured nationwide. With exceptions, LAGB and LSG are largely covered in all provinces. Patient wait times may be as high as 5-10 years. (Martin 2011)

- France: Bariatric and metabolic surgery is covered under National Health Insurance, and awareness of the benefits of bariatric and metabolic surgery is high among both patients and providers bariatric and metabolic surgery. (Lazzati 2013) Some post-operative nutritional supplements and follow-up operations are not covered. (Lazzati 2013)

- UK: A new national specialized commissioning policy from NHS England reportedly improves overall access to bariatric and metabolic surgery by following NICE guidelines on BMI eligibility. (Baron 2013)

  i. Patients are expected to attend local specialist weight loss programs for more than a year before surgery can be considered. (Baron 2013)
ii. Compared to public hospitals, private hospitals provide faster access to surgery but do not result in improved long-term outcomes. (Afoke 2013)

• Germany: Bariatric and metabolic surgery is covered by the public health system as a standard coverage benefit.

  i. Statutory health insurance (SHI) makes decisions on a case-by-case basis since bariatric and metabolic surgery is indicated only after failing of multi-modal weight loss programs. (Weiner 2013)

• Australia and New Zealand: RYGB, LAGB, and LSG are covered by Medicare, however not all surgical costs are covered by Medicare due to the difference in amount that the surgeon charges to patients and the benefit levels set by Medicare. However, partial coverage of costs leads to limited access in high-need but low-income populations.

• Taiwan: Coverage of bariatric and metabolic surgery is limited due to the low volume of the procedure and limited numbers of qualified surgeons in the country. (Buchwald 2013)
CHAPTER

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CHAPTER 3
Appendix
COST EFFECTIVENESS/ BENEFIT ANALYSIS

CEA

Asian Pacific


Europe, Middle East and Africa


Latin America


North America


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**Latin America**


**North America**


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