Bariatric Surgery

Clinical Expert

Richard John Lindquist MD

Medical Director, Swedish Weight Loss Services
**Disclosure**

Any unmarked topic will be considered a "Yes".

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**Clinical Advisor Novo Nordisk 2014**

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If yes to #7, provide name and funding sources:

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I certify that I have read and understand this Conflict of Interest form and that the information I have provided is true, complete, and correct as of this date.

X [Signature] [Date]  
R. Lindquist MD  
Print Name

So we may contact you regarding this information, please provide the following:

**Email Address:** Richard.Lindquist@swedish.org

**Phone Number:** 206. 465. 6905 (cell)
Full Name: Richard John Lindquist MD

Hm. Address: 1310 Minor Ave.
Apt. 508
Seattle, WA  98101

Wk. Address: Swedish Weight Loss Services
801 Broadway
Suite 800
Seattle, WA  98122

Ph: Home: 541.687.2879
Cell: 206.465.6905 (best number)
Work 206.215.2090
Fax (work): 206.215.3099

Personal e-mail: Rick_Lind@comcast.net
Professional e-mail: richard.lindquist@swedish.org

Professional/Personal Affiliations:

- Member, American Society of Bariatric Physicians (ASBP)
  - www.asbp.org
  - Member, Board of Trustees
  - 2013 Bariatrician of the Year
    - The Bariatrician of the Year award is presented annually and recognizes a physician who has done the most to advance the field of bariatric medicine and the Society
- Member, American Society for Metabolic and Bariatric Surgery
- Trustee, WA State Chapter, American Society for Metabolic & Bariatric Surgery (ASMBS)
- Member, The Obesity Society
- Trustee, Obesity Treatment Foundation
- Exam writer, American Board of Obesity Medicine
- Member, Obesity Action Coalition
- Member, American Academy of Family Physicians (AAFP)
- Vice Chair IRB Swedish Medical Center (2009 – current)
- Board Certified Family Medicine
  - American Board of Family Medicine
- Board Certified Bariatric Medicine
  - American Board of Obesity Medicine
- Fellow, American Academy of Sports Physicians
- American Heart Association:
  - Past National Faculty ACLS (Advanced Cardiac Life Support)
    - Engaged in leadership, development and QA of Advanced Cardiac Life Support (ACLS) materials and training on national level; Involved in QA national AHA ECC training.
  - Past Chair, ECC Committee, Oregon and SW Washington
    - Responsible for leadership in the training and quality assurance aspects of emergency cardiovascular care.
- State of Oregon EMS Medical Director of the Year 2001
  - Provided training, medical direction and quality assurance over 27 Fire/EMS agencies and approximately 800 First Responders in Linn, Lane and Douglas Counties in central and south Willamette Valley from 1990 through 2005. Included volunteer and paid departments including Reach air medical transport.
- Rotary International
  - Past President, Eugene Metropolitan Rotary Club
- American Academy of Family Physicians 2013-2014
  - Featured National Obesity Medicine Speaker “Chapter Speaker”
- Frequent national presenter on Obesity topics and metabolic syndrome
- Consultant Esai Pharmaceuticals
  - Obesity Medicine presentation
- Consultant Novo Nordisk Pharmaceuticals
  - Obesity Clinicians Advisory Board

Employment History:

Dec. 2014-current
Medical Director
Swedish Weight Loss Services
Swedish Medical Center
Seattle, WA

Duties include engagement with administration in development of medical and surgical service lines in a comprehensive weight management program. Involved in program planning and implementation, day to day clinic operations, quality assurance, and direct patient care. Provide support to other Swedish service lines and providers. Act as resource to administration on obesity care programs and planning.
June 2009-Dec. 2014  
Medical Program Director  
Swedish Weight Loss Services  
Swedish Medical Center  
Seattle, WA

Duties: Coordinate Medically Supervised Weight Loss programs for non surgical and surgical patients (pre, peri, and post op). Develop outreach, marketing and retail aspects of comprehensive surgical and medical program. Train R.N., ARNP, and PA staff. Develop operational aspects of comprehensive non surgical and surgical programs. Provide direct patient care to overweight and obese patients. Develop research program to further care of overweight and obese patients.

Program development focus has been developing weight management and chronic disease infrastructure within the Providence Health and Services and Swedish Health Services institutional organizations. Work has been centered around dyad of diabetes and obesity with target goal to develop improved system wide work flow and metric analysis in context of excellent patient care.

Most recent work includes outreach into teen (adolescent) wellness clinics, post partum weight control in a patient health center, development of program for pregnant women with obesity, and chronic disease models for diabetes and obesity.

2005 - 2009  
Clinical Medical Director  
Monarch Medical Weight Loss Centers  
Eugene, OR.

Hire, train, and supervise Physicians, Nurse Practitioners, Physician’s Assistants and Nurses for a multi clinic Bariatric Medicine Group. Involved in program development, medical protocols, site supervision, quality assurance, and direct patient care. Actively involved in marketing and presentations to employers, hospitals, businesses, public agencies, physicians’ groups and others via direct contact, television and news media, and public presentations.

1996 – 2006:  
Physician, Emergency Department  
McKenzie-Willamette Medical Center  
Springfield, Or.

2002-2009:  
“Relief” Physician, University Health Center  
University of Oregon  
Eugene, Or.

1989 – 2002:  
Staff Physician, University Health Center  
Vice Chair U of O IRB (1993-2002)  
University of Oregon  
Eugene, Or.
1990-1995:
Physician
PeaceHealth Urgent Care Clinic
Eugene, Or.

1987 – 1989:
Assistant Professor, Dept. of Family Medicine
University of South Florida
Tampa, Fl.

1987 – 1988:
Physician, Emergency Department
Palms of Pasadena Hospital
St. Petersburg Beach, Fl.

1986 – 1988:
Physician, Emergency Department
Bayfront Medical Center
St. Petersburg, Fl.

Education:
Doctor of Medicine 1984
University of Washington

Family Practice Residency 1984-87
Bayfront Medical Center
St. Petersburg, Fl.

Medical Director’s Course 2005
National Association of EMS Physicians

Board Preparation pathway and courses
American Board of Bariatric Medicine

Swedish University 2014
Physician Leadership Development
Seattle, WA
Background

- Estimates are that 14.5% of the U.S. population have BMI ≥ 35;
- Obesity is a chronic disease with associated complications;
- Medical and behavioral management of obesity is often ineffective;
- Given the lack of effective medical treatment, bariatric surgery is commonly performed to treat obesity.
Background: Types of Bariatric Surgery

- Adjustable gastric banding (LABG)
- Vertical sleeve gastrectomy (VSB)
- Roux-en-y bypass (RYGB)
- Biliopancreatic diversion (with or without duodenal switch) (BPD+DS)

Agency Medical Directors’ Concerns

- Safety = High
- Efficacy = High
- Cost = High
Key Questions

1. What is the comparative clinical effectiveness of bariatric procedures vs conventional weight-loss management in:
   a. Adults (≥ 21 yrs)
   b. Children (< 21 yrs), on an overall basis and by specific age groups.

2. What components of the management of patients undergoing bariatric surgery appear to be correlated with higher levels of “treatment success“?

3. What are the potential short- and long-term harms of bariatric surgery procedures, including rates of procedure-specific and general surgical complications, longer-term morbidity, mortality, and requirements for procedure revisions and/or reversal?

4. What is the differential effectiveness and safety of bariatric surgery procedures according to health-system and/or program factors?

5. What is the differential effectiveness and safety of bariatric surgery procedures according to patient and/or clinical factors?

6. What are the costs and cost-effectiveness of the major bariatric surgery procedures of focus in this evidence review?
Pediatric Bariatric Surgery:
Prior HTCC Coverage Decision

- Pediatric bariatric surgery for patients under age 18 is not a covered benefit due to insufficient evidence to conclude that it is safe, efficacious, and cost-effective.

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Pediatric Bariatric Surgery:
Prior HTCC Coverage Decision

- Pediatric bariatric surgery for patients 18-20 is a covered benefit only under the criteria identified in the reimbursement determination

- Indications and limitations of coverage:
  - Patients 18-20 years old
  - Bariatric surgical procedure of laparoscopic adjustable gastric banding only
  - Patients must meet and abide by all other agency bariatric surgery program criteria
Current State Agency Policy

**PEBB**
- BMI of 40 or over; or
- BMI of 35 to 39 with a diagnosis of diabetes OR at least 2 of the following co-morbid conditions (that have not responded to medical management and are expected to improve following bariatric surgery):
  - Hypertension
  - Dyslipidemia
  - Coronary heart disease
  - Sleep apnea

**Medicaid**
- BMI 35 or greater and age 21-59 yrs, with one of the following conditions:
  - Type 2 diabetes;
  - DJD of a major weight bearing joint AND candidate for joint replacement if weight loss is achieved;
  - Other rare co-morbid conditions where there is medical evidence that bariatric surgery is medically necessary and benefits outweigh risks.
Bariatric Surgery

Number of Bariatric Surgeries for Total Apple Health Population 2010 - 2013

- Lapband
- Lapband Revision
- Lapband Removal
- Lapband Replacement
- Lapband Repair
- Roux Y
- Roux Y Revision
- VSG

Note: Claim data extracted from MCSource for CY2010-2013.

UMP Non-Medicare Bariatric Surgeries 2010-2013*

- Lapband
- Roux en Y
- VSG
- Lapband Removal
- Lapband Replacement
- Lapband Repair
- Lapband Revision
- Roux Y
- Roux Y Revision

Note: Claim data extracted from MCSource for CY2010-2013.
Bariatric Surgery: Effectiveness

- Most observational studies suggest that bariatric surgery improves survival in severe obesity
- Bariatric surgery is more effective than medical management in the short term (1-2 years) with respect to:
  - Weight loss
  - Resolution of comorbidities
- Few bariatric surgery studies report valid long term results
Bariatric Surgery: Comparative Effectiveness Across Procedure Types

- RYGB and VSG have similar short term outcomes with respect to weight loss and impact on co-morbidities.
- RYGB and VSG lead to greater short term weight loss and resolution of comorbidities compared with LAGB.
- BPD/DS results in greater weight loss than RYGB.
- RYGB has better long term outcomes (i.e. 5 yrs) than LAGB in terms of weight loss and improvement in co-morbidities.

Bariatric Surgery: Safety

- Perioperative mortality associated with bariatric surgery appears to be in the range of 1%:
  - Perioperative mortality varies by procedure and approach.
  - Lowest mortality for LAGB and VSG; higher for laparoscopic RYGB; highest for RYGB and BPD.
Bariatric Surgery: Safety

- Perioperative complication rates vary by procedure
  - Broad range of estimates
  - Vary by procedure type and approach
- In 1 large prospective study\(^*\) (N=4776) with standardized data collection that used a composite end point for complications, rates across procedures were:
  - 1.0% LAGB
  - 4.8% Laparoscopic RYGB
  - 7.8% RYGB


Comparative Effectiveness and Safety in Children and Adolescents

- Limited data suggests that LAGB is effective in adolescents in achieving substantial weight loss and improving co-morbidities
- RYGB in one retrospective study did not appear superior to LAGB
- There is a lack of short and long term data evaluating safety in children and adolescents
Management Components Associated with Treatment Success

- Diverse and inconsistent literature regarding program and/or patient selection factors associated with greater treatment success
- Several studies found lower rates of surgical participation and follow-up post-surgery in patients with phobias, anxiety disorders, or other Axis 1 conditions

Differential Outcomes: Program Factors

- Surgeon experience/volume
  - Outcomes better with high-volume surgeons/centers vs. low volume (generally, <50 procedures/yr)
- Evidence mixed on outcomes at accredited and non-accredited facilities
- Evidence suggests better outcomes with multidisciplinary care
- Pre-/post-operative support:
  - No consistent evidence of pre-op weight loss on outcome; no evidence for pre-op dietary counseling; better evidence for post-op dietary counseling and support
Cost-Effectiveness

- Published evidence accumulated to date suggests that bariatric surgery meets commonly-accepted thresholds for cost-effectiveness in comparison to standard care across multiple BMI categories, time horizons and procedure types.

Medicare Coverage Decision

2009 NCD:

- RYGB, BPD with DS, and LAGB covered for beneficiaries who meet the following criteria:
  - BMI ≥ 35
  - One or more obesity-related co-morbidities
  - Failed prior medical treatment for obesity
  - (The NCD specifically states that type 2 DM should be considered a co-morbidity for purposes of coverage, but makes no specific mention of any other obesity-related co-morbidities)
- Open adjustable gastric banding and open VSG are non-covered
Local Medicare Coverage Decision

- Noridian Healthcare Solutions LCD for Washington covers laparoscopic VSG if patients meet the Medicare NCD criteria AND are younger than 65.

State Agency Recommendation: Adults (>21 years)

- Cover for BMI of ≥ 40 without comorbidities
- Cover for BMI of ≥ 35 < 40 for those patients:
  - With at least 1 obesity related co-morbid condition AND
  - Failed medical management
- Non-covered for BMI ≥ 30 < 35
- Where covered, patients must abide by all other agency surgery program criteria (e.g. specified centers or practitioners; pre-op psychological evaluation; participation in pre- and post-operative multidisciplinary care programs)
State Agency Recommendations: Pediatric Bariatric Surgery

- Non-covered for patients under age 18
- Pediatric bariatric surgery for patients 18-20 is a covered benefit only under the criteria identified in the reimbursement determination
- Indications and limitations of coverage:
  - Patients 18-20 years old
  - Bariatric surgical procedure of laparoscopic adjustable gastric banding only
  - Patients must meet and abide by all other agency bariatric surgery program criteria

Questions?

More Information:

Dan Lessler, MD
Daniel.Lessler@hca.wa.gov
**Order of Scheduled Presentations:**

**Bariatric Surgery**

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<tr>
<td>1</td>
<td>Robert Michaelson, MD, PhD, FACS, FASMBS</td>
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<td></td>
<td>President, Washington State Chapter, American Society for Metabolic and Bariatric Surgery</td>
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I am a bariatric surgeon and the current president of the Washington Chapter of the American Society for Metabolic and Bariatric Surgery.

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Signature: [Redacted]  Date: 4/30/15  Print Name: Robert Michaelson

So we may contact you regarding your presentation, please provide the following:

Email Address: rmichaelson@awws.com

Phone Number: (425) 238-9370
WA –ASMBS Public Comments:  
Washington State Health Care Authority  
Health Technology Assessment

Bariatric Surgery

Robert Michaelson, MD, PhD, FACS, FASMBS  
President, WA-ASMBS

SOS Should Not Have Been Excluded

Attrition of the sample also appeared to be a common concern across studies, from small single-center evaluations to large registry studies. Even the widely cited Swedish Obese Subjects (SOS) study, a matched prospective examination of bariatric surgery and nonsurgical management, saw a precipitous drop-off in patient availability after two years of follow-up (Sjostrom, 2013; Sjostrom, 2014). (Note: this study is not included in our primary analysis because over two-thirds of patients received gastroplasty, a procedure no longer performed in the U.S.). Large-scale patient attrition is certainly understandable in these patients, given the clinical and mental complexity involved in obesity-related illness and the attendant difficulties for patients in adhering to post-procedure follow-up programs; however, very few studies accounted for patient attrition using well-accepted methods such as survival analysis and/or actuarial reporting. In all other studies, concerns with observing long-term results only in a small

• WA-ASMBS considers this exclusion inappropriate
Vertical Banded Gastroplasty

Restrictive and non-adjustable

Adjustable Gastric Banding

Restrictive and adjustable

Most Common Surgical Options

Gastric Banding

Restrictive and adjustable

Gastric Sleeve

Restrictive

Gastric Bypass

Restrictive and malabsorptive
Swedish Obesity Subjects Trial

ASMBS Position

Exclusion of SOS is inappropriate for the following reasons:

- Weight loss with VBG (approximately 15% long-term) is in the range seen currently with adjustable gastric banding
- The 15% weight loss, while less than that associated with other procedures, still greatly exceeds the weight loss for all non-surgical comparative groups, particularly at two years and beyond
- The SOS trial does provide the opportunity to examine the benefits of greater weight loss on long-term outcomes compared to those that can be achieved by non-surgical interventions
- WA-ASMBS feels that the SOS is one of the most comprehensive and highly regarded studies in the bariatric surgical literature and its contribution should have been included in the analysis
1985 Obesity* Trends Among U.S. Adults

1995 Obesity* Trends Among U.S. Adults

*BMI ≥ 30, or ~30 lbs. overweight for a 5'4" person

Source: BRFSS, CDC.
2005 Obesity* Trends Among U.S. Adults

Source: BRFSS, CDC.

*BMI $\geq 30$, or ~30 lbs. overweight for a 5’4” person

2013 Obesity* Trends Among U.S. Adults

Source: BRFSS, CDC.

*BMI $\geq 30$, or ~30 lbs. overweight for a 5’4” person
Obesity Prevalence

Despite 30 years of:

- Diet
- Exercise
- Behavioral Modification

http://www.cdc.gov/diabetes/data/index.html

Washington Obesity Related Disease 2010 - Projected 2030

Current cases of Disease 2010
Projected cases of Disease 2030

http://stateofobesity.org/states/wa/
BARIATRIC SURGERY
Losing 50% to 70% of excess weight may be just the beginning...

Resolution of Co-morbidities after Bariatric Surgery

- Migraines: 51% resolved
- Peptic ulcer disease: 96% resolved
- Hypertension: 91% resolved
- Hypothyroidism: 89% resolved
- Metabolic syndrome: 92% resolved
- Type 2 diabetes: 82% resolved
- Urinary stress incontinence: 44% resolved
- Osteoarthritis/Regenerative joint disease: 41% resolved
- Depression: 45% reduced
- Obstructive sleep apnea: 74% resolved
- Asthma: 80% reduced
- NASH: 90% reduced
- GERD: 72% resolved
- Polycystic ovarian syndrome: 70% resolution of hirsutism
- 100% resolution of menstrual dysfunctions
- Venous stasis disease: 91% resolved
- Gout: 71% resolved

- AMA officially recognized obesity as a disease June 19, 2013.
NIH Recommendations for Treating Obesity
Based on BMI

A growing consensus favors bariatric surgery

- “Bariatric surgery should be considered for adults with BMI $\geq 35$ kg/m$^2$ and type 2 diabetes, especially if the diabetes is difficult to control with lifestyle and pharmacologic therapy.”
  - American Diabetes Association (2009)

- “When indicated, surgical intervention leads to significant improvements in decreasing excess weight and co-morbidities that can be maintained over time.”
  - American Heart Association (2011)

- “Bariatric surgery is an appropriate treatment for people with type 2 diabetes and obesity not achieving recommended treatment targets with medical therapies”
  - International Diabetes Federation (2011)

- “The beneficial effect of surgery on reversal of existing DM and prevention of its development has been confirmed in a number of studies”
  - American Association of Clinical Endocrinologists (2011)

- “…remission of diabetes, even if temporary, will lead to reduction in the progression to secondary complications of diabetes.”
  - Endocrine Society (2012)

Obesity’s cost is in direct medical costs
Increased medical costs in patients with higher levels of obesity

Economics: Direct Costs

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<th>2018</th>
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<tr>
<td>United States</td>
<td>$164 Billion (10%)</td>
<td>$344 Billion (21%)</td>
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<td>Washington</td>
<td>$1.59 Billion</td>
<td>$7.23 Billion</td>
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• Assuming obesity rates continue at their current level


Obesity’s cost is in medical utilization
Greater medical utilization compared to normal weight


Reduced Prescription Use - Diabetic patients
Patients discontinuing medications after bariatric surgery

Obesity’s cost is in decreased productivity

Days affected due to obesity

Obesity-related job absenteeism costs $4.3 billion annually

Morbid obesity’s cost is in lost workdays
Decreased productivity compared to normal weight persons
Morbid obesity’s cost is in more claims
More worker’s comp claims compared to normal weight

Per 100 FTE

Rate of Worker’s Compensation Claims

[Graph showing the rate of worker’s compensation claims for normal weight and morbid obesity (BMI ≥ 40)]


Current Approach to Obesity

- **HPI:** 34 y Female in NAD presents for annual PE
- **Assessment & Plan**
  - Heart Disease - cardiology
  - Diabetes – endocrinology
    - Kidney Failure – Nephrology
    - Peripheral Neuropathy – Neurology
    - Retinopathy - Ophthalmology
  - High BP – internal med
  - Sleep Apnea – pulmonology
  - Osteoarthritis – ortho
  - PCOS; infertility – Ob-Gyn
  - GERD – GI
  - Breast Cancer
    - General Surgery
    - Oncology
    - Rad Onc

254 lbs  BMI 42
Desirable Approach

- HPI: 31 y Morbidly Obese Female in NAD
- Assessment & Plan
  - Heart Disease – weight loss
  - Diabetes - weight loss
  - High Blood Pressure – weight loss
  - Sleep Apnea – weight loss
  - Osteoarthritis – weight loss
  - Infertility; PCOS – weight loss
  - GERD - weight loss

The WA-ASMBS strongly supports the addition of Bariatric Surgery to the Washington State Health Care Programs

“There is no other modality in all of medicine that can cure so many conditions with a single intervention”

Harvey Sugerman, M.D.
President ASBS, 2004-2005
Bariatric Surgery

An Assessment of Comparative Clinical Effectiveness & Comparative Value

Presented to the Washington State Health Care Authority by
Daniel A. Ollendorf, PhD
May 15, 2015

Overview

- Project Scope, Comparators, Outcomes of Interest
- Systematic Review of Published Evidence
- Comparative Value
- Evidence Ratings
- Clinical Guidelines
- Payer Coverage Policies
- Summary
Background

- Over one-third of American adults and nearly 20% of adolescents classified as obese
- Obesity and clinical sequelae (diabetes, cardiovascular disease, sleep apnea, etc.) generate nearly $150 million in healthcare costs in U.S.
- Historical treatment options limited in effectiveness (lifestyle changes) and/or restricted by safety concerns (older weight-loss medications)

Background

- Bariatric surgery
  - Umbrella term for group of procedures that involve modifications to digestive tract to promote weight loss
  - First procedures performed in 1950s; steady increase in use and further innovation as prevalence of severe/morbid obesity increased
  - 1991 NIH consensus conference cemented role of bariatric surgery in patients with morbid (BMI ≥40) obesity or those with severe (35-39.9) obesity and related comorbidity
Bariatric Surgery: Questions

- Balance of benefits and harms in patients with lower levels of obesity (BMI 30-35 or lower) and comorbidity
- Durability of treatment effect and long-term outcomes:
  - <3% of over 1,000 long-term studies retained sufficient numbers of patients for evaluation

*Puzziferi JAMA. 2014;312(9):934-942.

Most Common Bariatric Procedures in U.S.

- Adjustable gastric banding (LAGB)
- Vertical sleeve gastrectomy (VSG)
- Roux-en-y gastric bypass (RYGB)
- Biliopancreatic diversion (with or without duodenal switch) (BPD±DS)
Key Questions

1. What is the comparative clinical effectiveness of bariatric surgery procedures versus conventional weight-loss management in:
   a. Adults (i.e., age 21 years and older)?
   b. Children (age <21), on an overall basis and by specific age groups (i.e., 18-20, 13-17, 12 or less)?

2. What components of the management of patients undergoing bariatric surgery (e.g., selection of candidates for surgery, multi-disciplinary care team, pre- and/or post-procedure counseling and support) appear to be correlated with higher levels of “treatment success” (e.g., sustained weight loss, reduction in comorbidity burden, etc.)?

3. What are the potential short- and long-term harms of bariatric surgery procedures, including rates of procedure-specific and general surgical complications, longer-term morbidity, mortality, and requirements for procedure revision and/or reversal?

4. What is the differential effectiveness and safety of bariatric surgery procedures according to health-system and/or program factors such as:
   a. Surgeon experience
   b. Procedure volume
   c. Certification of surgery center
   d. Members of core team
   e. Type of pre-procedure preparation/post-procedure support
Key Questions

5. What is the differential effectiveness and safety of bariatric surgery procedures according to patient and/or clinical factors such as:
   a. Age, Gender, Race/ethnicity
   d. BMI (assessed as both continuous and categorical variable)
   e. Presence of comorbidities (e.g., hypertension, type 2 diabetes)
   f. Prior event history (e.g., myocardial infarction, stroke)
   g. Smoking status
   h. Psychosocial health
   i. Pre/post procedure adherence with program recommendations

6. What are the costs and cost-effectiveness of the major bariatric surgery procedures of focus in this evidence review?

Project Scope

Population:
- Adults and children undergoing bariatric surgery for obesity (mean BMI 30+)
- Evidence stratified in multiple ways (incl. BMI range, specific comorbidities, age range, etc.)

Surgical Procedures:
- RYGB
- LAGB
- VSG
- BPD±DS
**Project Scope**

**Comparators**
- “Active” nonsurgical management (e.g., medication, lifestyle intervention, counseling, exercise, etc.)
- Excluded wait-list and other controlled studies without active comparator
- Head-to-head studies of surgical procedures also assessed

**Project Scope**

**Outcomes:**
- Overall and obesity-related mortality
- Change in body weight/body mass
- Improvement/remission of comorbidities
- Health-related quality of life
- Harms:
  - Peri-operative mortality and complications
  - Procedure revision or reversal
  - Long-term complications (e.g., malabsorption)
**Literature Search**

- Published studies Jan 2000 – March 2015
- Randomized controlled trials (RCTs) and comparative observational studies included without restriction
- Case series limited based on follow-up (2+ years) and sample size:
  - Adults: 100 patients
  - Children: 25 patients

**Study Quality/Strength of Evidence**

- RCTs/Cohorts: USPSTF Criteria (see Appendix)
- Strength of Evidence
  - Risk of bias: study design and quality
  - Consistency: direction and magnitude of findings
  - Directness: direct comparison of major interventions and/or direct measurement of key outcomes
  - Precision: confidence interval around estimates of intervention effect
Findings
Quality & Type of Evidence

- Substantial and growing comparative evidence base, but issues of quality and applicability
  - Only 26 (15%) of 179 comparative studies considered of good quality
- Quality concerns observed:
  - Treatment group imbalances, even with body weight
  - Systematic differences in duration and/or high rate of loss to follow-up
  - Lack of use of appropriate statistical techniques to control for clinical and/or follow-up differences

KQ1a: Effectiveness of Bariatric Surgery in Adults
### Bariatric Surgery in Adults

- Bariatric surgery results in greater sustained weight loss and resolution of comorbidities than nonsurgical management:
  - True for all 4 procedures of interest
  - Challenged by lack of long-term data on durability of effects
  - Comorbidity data nearly all focused on Type 2 diabetes
  - Data on weight regain and comorbidity recidivism very limited

- Surgery appears to significantly reduce all-cause mortality (risk reductions of 20-45% in available studies), but studies vary widely in terms of quality and level of attrition

- In head-to-head studies, BPD/DS appears to have greatest efficacy, followed by RYGB, VSG, and LAGB
### Mean BMI at Study End

<table>
<thead>
<tr>
<th>Study name</th>
<th>Statistics for each study</th>
<th>Difference in means and 95% CI</th>
<th>Heterogeneity: Tau^2= 2.81; Q=55.8; df=9; I^2=84%</th>
</tr>
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<tbody>
<tr>
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</table>

### Resolution of Type 2 Diabetes

<table>
<thead>
<tr>
<th>Study name</th>
<th>Statistics for each study</th>
<th>MHI log odds ratio and 95% CI</th>
<th>Heterogeneity: Tau^2= 1.58; Q=20.5; df=8; I^2=62%</th>
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</thead>
<tbody>
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<td>Test for overall effect: Z=6.32 (p&lt;0.001)</td>
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</tbody>
</table>
Studies in Patients with BMI <35

- Nine good-quality RCTs and comparative cohorts in our review
- 7/9 focused exclusively on patients with Type 2 diabetes
  - Most were studies of RYGB or LAGB (or both)
- All studies involved comparisons to nonsurgical lifestyle and diabetes management
- Resolution of diabetes substantially higher in surgical groups (range: 26-73%; median 42%) vs. nonsurgical management (range: 0-16%; median 9%)
- Two studies of metabolic syndrome also found significantly greater resolution in surgical groups

Weight-related Outcomes in Patients with BMI <35

<table>
<thead>
<tr>
<th>Procedure</th>
<th>% Decrease BMI Median</th>
<th>Range</th>
<th>% LWL Median</th>
<th>Range</th>
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<tr>
<td>RYGB</td>
<td>25.4</td>
<td>(19.6-34.3)</td>
<td>70.0</td>
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<td>VSG</td>
<td>21.3</td>
<td>(21.3-21.3)</td>
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<td>LAGB</td>
<td>16.8</td>
<td>(11.8-21.7)</td>
<td>87.2</td>
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<td>BPD/DS</td>
<td>31.8</td>
<td>(17.3-46.3)</td>
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<td>Follow-up (months)</td>
<td>12.0</td>
<td>(3.0-45.2)</td>
<td>18.0</td>
<td>(12.0-24.0)</td>
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<td>7</td>
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<td>2</td>
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<td>Good/Fair/Poor</td>
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## KQ1b: Effectiveness of Bariatric Surgery in Pediatric Populations

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<th>Study Information</th>
<th>Comparators</th>
<th>Risk of Bias</th>
<th>Consistency</th>
<th>Directness</th>
<th>Precision</th>
<th>Strength of Evidence</th>
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<td>Direct</td>
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<td>Direct</td>
<td>Imprecise</td>
<td>+</td>
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<td>N=900</td>
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<tr>
<td><strong>Children (&gt;12)</strong></td>
<td>RYGB</td>
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<td></td>
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<td></td>
<td>NO STUDIES</td>
</tr>
</tbody>
</table>

**Incremental Mean reduction in BMI: 9.8.**

**Complete resolution of metabolic syndrome in surgical arm.**

**Groups differed significantly at baseline; no differences after adjustment.**
Bariatric Surgery in Pediatrics

- Single RCT identified comparing LAGB to nonsurgical management*
  - 50 patients age 14-18, 69% female, mean BMI 41.4
  - Percentage excess weight loss (EWL) significantly higher in LAGB group (79% vs. 13%, p<.001) at 2 years
  - Metabolic syndrome completely resolved in 9/9 surgical patients vs. 6/10 nonsurgical patients (p=.025)
- Retrospective study from BOLD database** comparing RYGB to LAGB
  - 890 patients age 11-19, 75% female, mean BMI 51.4
  - Significant reductions in weight and significant improvement in hyperlipidemia, but differences no longer significant after statistical adjustment for between-group differences

27  *O'Brien, 2010; **Messiah, 2013

KQ2: Management Components Associated with Treatment Success
Management Components Associated with Treatment Success

- Diverse and inconsistent literature regarding program and/or patient selection factors associated with greater treatment success

- Several studies found lower rates of surgical participation and follow-up post-surgery in patients with phobias, anxiety disorders, or other Axis I conditions

- Multidisciplinary care (including dedicated dietary support after surgery) associated with better program adherence and greater sustained weight loss

- Post-operative peer support groups also associated with better weight-loss outcomes
# KQ3: Potential Harms of Bariatric Surgery

## Study Information

<table>
<thead>
<tr>
<th>Study Information</th>
<th>Comparators</th>
<th>Risk of Bias</th>
<th>Consistency</th>
<th>Directness</th>
<th>Precision</th>
<th>Strength of Evidence</th>
<th>Direction of Effect</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peri-operative Mortality</td>
<td>Total of 32 studies reporting harms (N=31,637)</td>
<td>High</td>
<td>Inconsistent</td>
<td>Indirect</td>
<td>Imprecise</td>
<td>Insufficient</td>
<td>Underreported (7% deaths in 32 studies)</td>
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<tr>
<td>Overall Complications</td>
<td>High</td>
<td>Inconsistent</td>
<td>Direct</td>
<td>Imprecise</td>
<td>++ Low</td>
<td>Median by proc: RYGB: 15.4, VSG: 9.5, LAGB: 17.9, BPD: 11.6</td>
<td>Inconsistent reporting and categorization of complications; RCTs underpowered to detect differences</td>
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</tr>
<tr>
<td>Reoperation</td>
<td>High</td>
<td>Inconsistent</td>
<td>Direct</td>
<td>Imprecise</td>
<td>++ Low</td>
<td>Median by proc: RYGB: 8.0, VSG: 2.0, LAGB: 14.8, BPD: 13.0</td>
<td>Inconsistent reporting and categorization of reoperations; RCTs underpowered to detect differences</td>
<td></td>
</tr>
</tbody>
</table>
Potential Harms of Bariatric Surgery

- Literature challenged by:
  - Rating of complication severity done inconsistently or not at all
  - Harms underreported in many studies (e.g., peri-operative mortality)
  - Most studies underpowered to detect differences in even relatively common complications
  - High variability in available estimates

- Across procedures:
  - BPD/DS has the highest median overall complication rate (32%), but based on very small sample of patients
  - LAGB has the highest reoperation rate (15%), vs. 2-13% for other procedures
  - VSG has the lowest median complication and reoperation rates

### Median complication and reoperation rates for all good and fair quality RCTs and prospective comparative cohort studies, by procedure

<table>
<thead>
<tr>
<th>Procedure</th>
<th># of studies</th>
<th># of patients</th>
<th>Follow-up; range, median (months)</th>
<th>Complication rate; range, median (%)*</th>
<th>Reoperation rate; range, median (%)</th>
<th># of deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>BPD</td>
<td>7</td>
<td>189</td>
<td>12-60, 18</td>
<td>17-79, 31.6</td>
<td>3-45, 13.0</td>
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<tr>
<td>LAGB</td>
<td>14</td>
<td>13,005</td>
<td>12-120, 24</td>
<td>3-61, 17.9</td>
<td>1-33, 14.8</td>
<td>11</td>
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<td>RYGB</td>
<td>26</td>
<td>15,830</td>
<td>1-120, 16</td>
<td>0-78, 19.4</td>
<td>0-33, 6.0</td>
<td>62</td>
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<tr>
<td>VSG</td>
<td>12</td>
<td>2,613</td>
<td>12-36, 12</td>
<td>1-80, 9.5</td>
<td>0-17, 2.0</td>
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</table>

*Complication rate may include reoperations in some studies.

BPD = Biliopancreatic Diversion, LAGB = Laparoscopic Adjustable Gastric Banding, RYGB = Roux-en-Y Gastric Bypass, VSG = Vertical Sleeve Gastrectomy
Potential Harms of Bariatric Surgery

<table>
<thead>
<tr>
<th>Procedure</th>
<th># of Studies</th>
<th># of Patients</th>
<th>Follow-Ups Range, Median (Months)</th>
<th>Complication Rate: Range, Median (%)</th>
<th>Reoperation Rate: Range, Median (%)</th>
<th>Mortality Rate: Range, Median (%)</th>
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<tr>
<td>BPD</td>
<td>9</td>
<td>2,659</td>
<td>3-63 (24)</td>
<td>8-83, 26.9</td>
<td>0-30, 3.6</td>
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<td>0-44, 7.4</td>
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<td>RYGB</td>
<td>23</td>
<td>840,885</td>
<td>2-72 (29)</td>
<td>0-78, 9.2</td>
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<td>0-4-3, 1.94</td>
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<td>11</td>
<td>16,574</td>
<td>2-63 (23)</td>
<td>0-80, 8.8</td>
<td>0-17, 3.9</td>
<td>0-3-9, 0.07</td>
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</table>

*B complication rate may include reoperations in some studies.

BPD = Bilopancreatic Diversion, LAGB = Laparoscopic Adjustable Gastric Banding, RYGB = Roux-en-Y Gastric Bypass, VSG = Vertical Sleeve Gastroctomy

KQ4: Differential Effectiveness and Safety by Health-System or Program Factors
Differential Outcomes: Program Factors

- Surgeon experience/volume:
  - Learning curve (~70-250 procedures)
  - As with other surgical procedures, outcomes better with high-volume surgeons/centers vs. low-volume (generally, <50 procedures/yr)

- Certification/accreditation:
  - Evidence mixed on outcomes at accredited vs. non-accredited facilities

- Multidisciplinary care:
  - Evidence suggests better outcomes, but also an accreditation requirement

- Pre-/post-operative support:
  - No consistent evidence of pre-operative weight loss on outcome, no evidence for pre-operative dietary counseling; better evidence for post-operative dietary and counseling support
### KQ5: Differential Effectiveness and Safety by Patient Factors

<table>
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<tr>
<th>Study Information</th>
<th>Comparators</th>
<th>Risk of Bias</th>
<th>Consistency</th>
<th>Directness</th>
<th>Precision</th>
<th>Strength of Evidence</th>
<th>Direction of Effect</th>
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<td>No consistent effects of age, gender, or race</td>
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<td>++ Low</td>
<td>Yes</td>
<td>Best outcomes for BMI ≥40 vs. 30-39 and 50+ Comparison problematic across studies due to limited subgroup data</td>
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<td>Comorbidities/ Prior Events</td>
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<td>Yes</td>
<td>Certain comorbidities affect RYGB outcomes more than LAGB</td>
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<td>N/A</td>
<td>High</td>
<td>Inconsistent</td>
<td>Indirect</td>
<td>Imprecise</td>
<td>+ Insufficient</td>
<td></td>
<td>EWL lower in LAGB with poor pre-op program adherence, no effect for RYGB Single retrospective cohort</td>
</tr>
</tbody>
</table>

**Study Information**
- **Comparators**: N/A
- **Risk of Bias**: Medium
- **Consistency**: Inconsistent
- **Directness**: Direct
- **Precision**: Imprecise
- **Strength of Evidence**: ++ Low
- **Direction of Effect**: Yes
- **Comments**: No consistent effects of age, gender, or race
Differential Outcomes: Patient Factors

- Demographics:
  - No consistent evidence showing differential outcomes by treatment approach when stratified by age, gender, or race/ethnicity
- BMI:
  - Excess weight loss generally lower at higher BMI levels
  - No consistent weight loss patterns in studies stratifying by pre-operative BMI
- Comorbidities/Prior Event History
  - Limited evidence suggest CV comorbidities affect outcome more in RYGB than LAGB patients
- Program adherence:
  - Limited evidence of poorer outcomes among LAGB patients not adherent to pre-op program; no effect for RYGB

KQ6: Costs and Cost-Effectiveness of Bariatric Surgery
### Economic Impact of Bariatric Surgery: Published Evidence

- **Systematic review of 13 economic evaluations***:
  - Bariatric surgery produced incremental cost-effectiveness ratios consistently below $50,000 per QALY gained vs. nonsurgical management
  - Higher cost-effectiveness ratios with (a) shorter time horizons; and/or (b) lower levels of BMI (in some studies)

- **Claims-based evaluation****: 
  - Analysis of ~60,000 BCBS patients nationwide
  - Significant increase in costs in years 2 and 3 after surgery, decline to pre-operative levels thereafter
  - Costs higher in surgical group in each of the 6 years of the analysis

*Padwal, 2011; **Weiner, 2013
Economic Impact of Bariatric Surgery: ICER Simulation Model

- Two-part model of (a) short-term effects of surgery on weight loss, comorbidities, and adverse effects; and (b) longer-term effects of BMI reduction (10 years)
- Target Population:
  - Adult candidates for surgery
  - Overall and stratified by pre-operative BMI (30-34.9, 35-39.9, 40+)
- Strategies:
  - Surgery: RYGB, LAGB, VSG, BPD/DS
  - Conventional weight-loss treatments
- Costs
  - PEBB payments for surgery and complications, published literature for other costs (tied to BMI after treatment)

Economic Impact of Bariatric Surgery: ICER Simulation Model

- Key assumptions:
  - BMI reduction after treatment would erode over time for all interventions except for BPD/DS and conventional treatment
  - 30% reduction in all-cause mortality assumed for all types of surgery vs. conventional management (tested in sensitivity analyses)
  - Peri-operative risks included mortality, complications, and reoperation
  - Quality of life, survival, and costs tied to BMI level following treatment
  - Costs limited to direct medical-care costs only
  - Comorbidity resolution limited to diabetes, hypertension, and hyperlipidemia
Cost-Effectiveness of Bariatric Surgery, 10-year Timeframe (BMI 30+)

<table>
<thead>
<tr>
<th>BMI Level/Procedure</th>
<th>Cost ($)</th>
<th>Effectiveness (QALYs)</th>
<th>Cost-effectiveness ($/QALY gained)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Vs. SC</td>
<td>Vs. RYGB</td>
</tr>
<tr>
<td>BMIs30</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard care</td>
<td>$34,923</td>
<td>7.5680 NA</td>
<td>NA NA</td>
</tr>
<tr>
<td>RYGB</td>
<td>$54,110</td>
<td>8.0807 $37,423 NA</td>
<td>NA</td>
</tr>
<tr>
<td>VSG</td>
<td>$48,702</td>
<td>8.0417 $29,087 Less expensive &amp; less effective</td>
<td></td>
</tr>
<tr>
<td>LAGB</td>
<td>$47,668</td>
<td>7.9252 $35,680 Less expensive &amp; less effective</td>
<td></td>
</tr>
<tr>
<td>BPD/DS</td>
<td>$65,741</td>
<td>8.2307 $46,508 $77,574</td>
<td></td>
</tr>
</tbody>
</table>

Ratios least favorable for BMI 30-34.9, but still within generally-accepted levels for cost-effectiveness (e.g., ~$53,000, $43,000, and $31,000 per QALY gained for RYGB vs. standard care at BMI of 30-34.9, 35-39.9, and 40+ respectively)

Sensitivity Analyses

<table>
<thead>
<tr>
<th>Incremental cost per QALY</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>Base Case</td>
</tr>
<tr>
<td>Cost of RYBG procedure</td>
</tr>
<tr>
<td>BMI Trajectory</td>
</tr>
<tr>
<td>Increase in costs by BMI</td>
</tr>
<tr>
<td>Mean BMI</td>
</tr>
<tr>
<td>Discount rate</td>
</tr>
<tr>
<td>Mortality benefit of RYBG</td>
</tr>
</tbody>
</table>
Integrated Evidence Ratings

ICER Rating Matrix

<table>
<thead>
<tr>
<th>Superior: A</th>
<th>Aa</th>
<th>Ab</th>
<th>Ac</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incremental B*/B</td>
<td>B* a</td>
<td>B* b</td>
<td>B* c</td>
</tr>
<tr>
<td>Comparable C*/C</td>
<td>C* a</td>
<td>C* b</td>
<td>C* c</td>
</tr>
<tr>
<td>Inferior: D</td>
<td>Da</td>
<td>Db</td>
<td>Dc</td>
</tr>
<tr>
<td>Promising but Inconclusive: P/I</td>
<td>Pa</td>
<td>Pb</td>
<td>Pc</td>
</tr>
<tr>
<td>Insufficient: I</td>
<td>I</td>
<td>I</td>
<td>I</td>
</tr>
</tbody>
</table>

Comparative Value

a: High  b: Reasonable/Comp  c: Low
Evidence Ratings: Adults

- Bariatric Surgery vs. Nonsurgical Management
  - For BMI ≥ 35: B+b
  - For BMI 30-34.9 and T2DM: Bb
  - For BMI 30-34.9 and other comorbidities: I

- Comparing Surgical Procedures
  - VSG vs. RYGB: Cb
  - LAGB vs. RYGB: Db
  - BPD/DS vs. RYGB: Bb

Evidence Ratings: Adolescents/Children

- Adolescents:
  - Surgery vs. Nonsurgical management: Pb (for BMI ≥ 35)
  - VSG vs. RYGB: I
  - LAGB vs. RYGB: I
  - BPD/DS vs. RYGB: I

- Children (age <12):
  - I (Insufficient) for all comparisons
Clinical Practice Guidelines

Practice Guidelines

- AHA, ACC, TOS, AACE, ASMBS, VA/DoD (Adults)
- Consistent support for bariatric surgery for BMI $\geq 40$ and 35-39.9 with obesity-related comorbidities
- Some consideration of BMI 30-34.9 with diabetes or metabolic syndrome, but not for glycemic control alone
- VA/DoD considers evidence insufficient for patients age >65 or with BMI <35
- Endocrine Society (2007) recommends bariatric surgery for adolescents with BMI $\geq 50$ or $\geq 40$ with severe comorbid conditions and failure of lifestyle/medical intervention
### Payer Coverage Policies

### CMS

- 2009 NCD; coverage for:
  - BMI $\geq 35$; and
  - One or more obesity-related comorbidities
  - Failed prior medical treatment
- Open gastric banding and sleeve gastrectomy non-covered
- LCD for WA: Laparoscopic VSG covered but only for patients age $<65$
Private Payers

- National and regional payers generally cover bariatric procedures for adults with BMI ≥40 or ≥35 with obesity-related comorbidities
  - Most restrict coverage to those who have attempted medical weight loss for at least 6 months prior to surgery
  - Some require mental health evaluation prior to surgery
- Coverage for adolescents follows guidelines (BMI ≥50 or ≥40 with severe comorbidities) and is restricted to those who have nearly or completely finished bone growth
- Regence considers BPD±DS investigational and does not cover it

Appendix: Quality Criteria
Quality Ratings: USPSTF criteria

Outcome Studies:

- **“Good”:**
  - Comparable groups with no or low attrition; intent-to-treat analysis used in RCTs
  - Reliable and valid measurement instruments used
  - Clear description of intervention and comparator(s)
  - All important outcomes considered
  - Attention to confounders in design and analysis

- **“Fair”:**
  - Generally comparable groups, some differential follow-up may occur; intent-to-treat analysis used in RCTs
  - Acceptable measurement instruments used
  - Some but not all important outcomes considered
  - Some but not all potential confounders are accounted for

- **“Poor”:**
  - Noncomparable groups and/or differential follow-up; lack of intent-to-treat analysis for RCTs
  - Unreliable or invalid measurement instruments used (including not masking outcome assessment)
  - Key confounders given little or no attention
HTCC Coverage and Reimbursement Determination
Analytic Tool

HTA’s goal is to achieve better health care outcomes for enrollees and beneficiaries of state programs by paying for proven health technologies that work.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:
1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective\(^1\) as expressed by the following standards\(^2\):

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms\(^3\):

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

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\(^1\) Based on Legislative mandate: See RCW 70.14.100(2).
\(^2\) The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm
\(^3\) The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm
Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. **Availability of Evidence:**

   Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. **Sufficiency of the Evidence:**

   Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence\(^4\) using characteristics such as:
   - Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
   - The amount of evidence (sparse to many number of evidence or events or individuals studied);
   - Consistency of evidence (results vary or largely similar);
   - Recency (timeliness of information);
   - Directness of evidence (link between technology and outcome);
   - Relevance of evidence (applicability to agency program and clients);
   - Bias (likelihood of conflict of interest or lack of safeguards).

   Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

<table>
<thead>
<tr>
<th>Not Confident</th>
<th>Confident</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.</td>
<td>Very certain of evidentiary support. Further information is unlikely to change confidence</td>
</tr>
</tbody>
</table>

3. **Factors for Consideration - Importance**

   At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology’s safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy

\(^4\) Based on GRADE recommendation: [http://www.gradeworkinggroup.org/FAQ/index.htm](http://www.gradeworkinggroup.org/FAQ/index.htm)
Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

### HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

**Discussion Document:**
What are the key factors and health outcomes and what evidence is there?

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety</td>
<td>Safety</td>
</tr>
<tr>
<td>Death</td>
<td></td>
</tr>
<tr>
<td>Reoperation/revision/removal</td>
<td></td>
</tr>
<tr>
<td>Other medical complication(s)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Efficacy – Effectiveness</th>
<th>Efficacy / Effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decrease in BMI</td>
<td></td>
</tr>
<tr>
<td>Excess Weight Loss</td>
<td></td>
</tr>
<tr>
<td>Improved Type II DM</td>
<td></td>
</tr>
<tr>
<td>Improved other comorbidities</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Special Population / Considerations</th>
<th>Special Populations/ Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
</tr>
</tbody>
</table>
A 2009 national coverage decision (NCD) on coverage for bariatric surgery provides coverage for RYGB, BPD with DS, and LAGB for beneficiaries who meet the following criteria:

- BMI \( \geq 35 \)
- One or more obesity-related comorbidities
- Failed prior medical treatment for obesity

The NCD specifically states that type 2 diabetes should be considered a comorbidity for purposes of coverage, but makes no specific mention of any other obesity-related comorbidities.

Open adjustable gastric banding and open VSG are non-covered procedures. CMS allows Medicare Administrative Contractors (MACs) to make local coverage decisions (LCDs) on stand-alone laparoscopic VSG.

Noridian Healthcare Solution’s LCD for Washington covers laparoscopic VSG if patients meet the above three clinical criteria and are younger than age 65, as the evidence base to support VSG is felt to be too weak in older patients.

Clinical Guidelines and Training Standards
[FROM PAGE 7 OF FINAL EVIDENCE REPORT]

American Heart Association/American College of Cardiology/The Obesity Society (AHA/ACC/TOS) (2013)

http://content.onlinejacc.org
The AHA/ACC/TOS joint guidelines suggest that bariatric surgery is an appropriate option for patients with a BMI of at least 40kg/m\(^2\), or with a BMI of at least 35kg/m\(^2\) accompanied by an obesity-related comorbid condition. Surgical candidates must be motivated to lose weight, but have not experienced weight loss sufficient to achieve target health outcomes despite participation in behavioral treatment, with or without the addition of pharmacotherapy. AHA/ACC/TOS guidelines do not provide a preference on the type of bariatric procedure used, and instead suggest that choice of procedure should be based on patient factors such as age, severity of obesity, comorbid conditions, surgical risk factors, risk for short- and long-term complications, and behavioral and psychosocial factors. Guidelines suggest that evidence is insufficient to support the use of bariatric procedures in patients with a BMI less than 35kg/m\(^2\).

**American Association of Clinical Endocrinologists/The Obesity Society/ American Society for Metabolic and Bariatric Surgery (AACE/TOS/ASMBS) (2013)**

https://www.aace.com

Bariatric surgery should be considered for patients with a BMI ≥40kg/m\(^2\) who do not have existing medical complications and for whom surgery would not pose excessive risk. Patients with a BMI ≥35kg/m\(^2\) who have at least one comorbid condition, such as type 2 diabetes, hypertension, hyperlipidemia, or obstructive sleep apnea may also be eligible. Patients with a BMI between 30 and 34.9kg/m\(^2\) with comorbid diabetes or metabolic syndrome may be eligible, though there is less evidence on the effects of bariatric surgery in this patient population. Evidence is considered insufficient to recommend any bariatric procedure for glycemic control alone.

AACE/TOS/ASMBS guidelines state that evidence is currently insufficient to recommend one procedure over another, and suggest that procedure type should be based on individual goals, available regional expertise, patient preferences, and personalized risk stratification. Laparoscopic procedures are generally preferred over open ones. LAGB, LSG, RYGB, and BPD+DS are considered to be the primary procedures of interest, though the guidelines express concerns regarding greater risks of nutritional deficiency associated with BPD+DS.


http://www.healthquality.va.gov/guidelines/CD/obesity

Bariatric surgery should be offered in conjunction with lifestyle modification as an option for weight loss in adults with a BMI greater than 40kg/m\(^2\) or with a BMI of 35.0-39.9kg/m\(^2\) accompanied by one or more obesity-related comorbid conditions. Surgery can also be considered for improvement of obesity-related conditions aside from weight loss in some patients with a BMI over 35kg/m\(^2\). Current evidence is insufficient to support the use of bariatric surgery for weight loss or to improve comorbid conditions in patients over the age of 65 or with a BMI less than 35kg/m\(^2\). Patients who are candidates for bariatric surgery should be well-informed of the benefits and possible risks associated with the procedure. A consultation with a bariatric surgical team prior to surgery should be offered to patients who request more information. Following surgery, patients should be provided with lifelong follow-up services to monitor any adverse effects or complications, dietary needs, adherence to weight management behaviors, and psychological health.

**Original NIH-based Criteria**
Criteria originally promulgated by the U.S. National Institutes of Health are often cited in other clinical guidelines and payer coverage policies, despite their age. They are summarized here for completeness.

**National Heart, Lung, and Blood Institute (1998)**

http://www.nhlbi.nih.gov

Bariatric surgery is an option for weight loss in patients with severe obesity, characterized by a BMI $>40\text{kg/m}^2$ or $>35\text{kg/m}^2$ with comorbid conditions such as cardiovascular complications, sleep apnea, uncontrolled type 2 diabetes, or physical limitations that interfere with daily activities, in whom other methods of weight loss have failed and who are at high risk for obesity-related morbidity and mortality. Patients undergoing surgical intervention should be cared for by a multidisciplinary team that includes medical, behavioral, and nutritional components. Support should be available in each of these areas both before and after the procedure. Following surgery, patients should receive lifelong follow-up to monitor for vitamin deficiencies, gastrointestinal complications, or mood changes.

**Guidelines for Pediatric Surgery**

Clinical guidelines published regarding the use of bariatric procedures specifically in children are summarized below.

**Endocrine Society (2007)**

http://press.endocrine.org

For the treatment of obesity in children, the Endocrine Society recommends bariatric surgery for adolescents with a BMI above $50\text{kg/m}^2$, or with a BMI above $40\text{kg/m}^2$ with severe comorbid conditions in whom lifestyle modifications, with or without the use of pharmacotherapy, have been unsuccessful. Qualified adolescents and their families must be psychologically stable and able to adhere to lifestyle changes. Families must have access to experienced bariatric surgeons and multidisciplinary teams able to assess the benefits and risks of surgery.

**Selected ex-U.S. Guidelines**

Guidelines published by the U.K.’s National Institute for Health and Care Excellence (NICE) as well as the Canadian Medical Association are also summarized below.

**National Institute for Health and Care Excellence, UK (NICE) (2014)**

https://www.nice.org.uk/guidance

Bariatric surgery can be considered for treatment of obesity in patients with BMI $>40\text{kg/m}^2$ or $>35\text{kg/m}^2$ with severe comorbid conditions, such as type 2 diabetes or high blood pressure who meet the following criteria:

- Health and/or comorbidity would be improved with weight loss;
- Attempts at all appropriate non-surgical methods of weight loss have been made without adequate results;
- Have been receiving or will receive intensive medical management;
- Are suitable candidates for anesthesia and surgery; and
- Are able to commit to long-term follow-up.
Bariatric surgery is also recommended for patients with a BMI >50kg/m² in whom other interventions have not been effective. Expedited surgical assessment may be considered for patients with BMI ≥35kg/m² with recent-onset type 2 diabetes. Patients with BMI between 30 and 34.9kg/m² with recent-onset type 2 diabetes, as well as patients of Asian descent with recent-onset type 2 diabetes and a BMI below this range, may also be assessed for surgery.

Surgery is generally not recommended for children, but may be considered in exceptional circumstances in patients who have reached physiological maturity. Pediatric patients should be cared for by multidisciplinary teams with pediatric expertise. Pediatric patients should undergo psychological, educational, family, and social assessments before qualifying for surgery. They should also undergo a medical screening including genetic testing for rare but treatable causes of obesity.

**Canadian Medical Association (2007)**

[http://www.cmaj.ca](http://www.cmaj.ca)

Bariatric surgery is suggested for adults with clinically severe obesity, characterized by a BMI of >40kg/m² or ≥35kg/m² with severe comorbid conditions, in whom lifestyle intervention has not been adequate to reduce weight. In adolescents, surgery should be reserved for special cases and should be performed by experienced teams. When possible, a minimally invasive technique is recommended for all bariatric procedures. Recommended surgical options include vertical banded gastroplasty, LAGB, BPD+DS and RYGB. Care teams for bariatric patients should include a dietician, an internist, an anesthetist, a psychiatrist or psychologist, nurses, a respiratory physician, a physiotherapist and a social worker.

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**Clinical Committee Findings and Decisions**

**Efficacy Considerations**

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
For diagnostic tests, what is the evidence of a diagnostic tests’ accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

Safety
- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact
- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall
- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

Next Step: Cover or No Cover
If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions
If covered with conditions, the Committee will continue discussion.

1) Does the committee have enough information to identify conditions or criteria?
   - Refer to evidence identification document and discussion.
   - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
   - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.
2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:

- What are the known conditions/criteria and evidence state
- What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Clinical Committee Evidence Votes

First Voting Question
The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

<table>
<thead>
<tr>
<th></th>
<th>Unproven (no)</th>
<th>Equivalent (yes)</th>
<th>Less (yes)</th>
<th>More (yes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safe</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost-effective</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Discussion
Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
• Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second Vote
Based on the evidence about the technologies’ safety, efficacy, and cost-effectiveness, it is

_____ Not Covered  ___ Covered Unconditionally  ____Covered Under Certain Conditions

Discussion Item
Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Next Step: Proposed Findings and Decision and Public Comment
At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

1) Based on public comment was evidence overlooked in the process that should be considered?

2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Next Step: Final Determination
Following review of the proposed findings and decision document and public comments:

Final Vote
Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome Chair will lead discussion to determine next steps.