

Bariatric Surgery

Clinical Expert

Richard John Lindquist MD

Medical Director, Swedish Weight Loss Services

WA - Health Technology Assessment

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of \$10,000.	X	
2.	Equity interests such as stocks, stock options or other ownership interests.		X
3.	Status or position as an officer, board member, trustee, owner.		X
4.	Loan or intellectual property rights.		X
5.	Research funding.		X
6.	Any other relationship, including travel arrangements.		X

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

Clinical Advisor NOVO NORDISK 2014

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		X

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

If you believe that you do not have a conflict, but are concerned that it may appear that you do, you may attach additional sheets explaining why you believe that you should not be excluded.

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 [Redacted Signature] [Redacted Date]

R. LINDQUIST MD. [Redacted 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
- Consulant 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



**Washington State
Health Care Authority**

Agency Medical Director Comments

**Bariatric Surgery:
Comparative Clinical Effectiveness & Comparative Value**

Dan Lessler, MD
Chief Medical Officer,
Washington Health Care Authority

May 15, 2015


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Bariatric Surgery

Background

- Estimates are that 14.5% of the U.S. population have BMI \geq 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.

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Bariatric Surgery

Background: Types of Bariatric Surgery

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

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Bariatric Surgery

Agency Medical Directors' Concerns

- **Safety = High**
- **Efficacy = High**
- **Cost = High**

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Bariatric Surgery

Key Questions

1. What is the comparative clinical effectiveness of bariatric procedures vs conventional weight-loss management in:
 - a. Adults (\geq 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?

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Bariatric Surgery

Key Questions

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?

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Bariatric Surgery

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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Bariatric Surgery

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

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Bariatric Surgery

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

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Bariatric Surgery

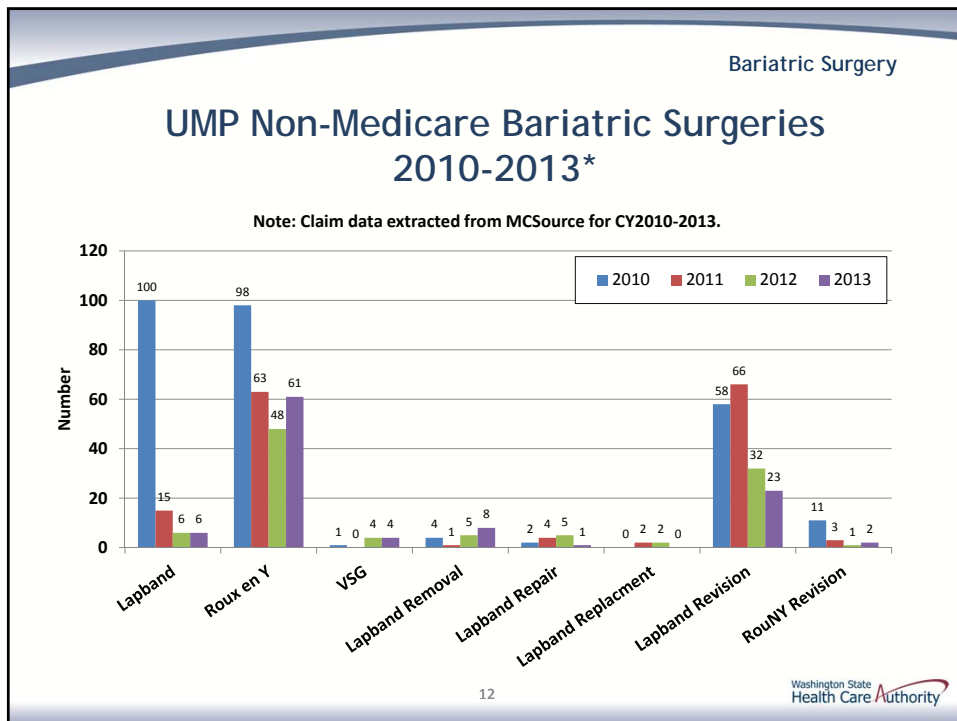
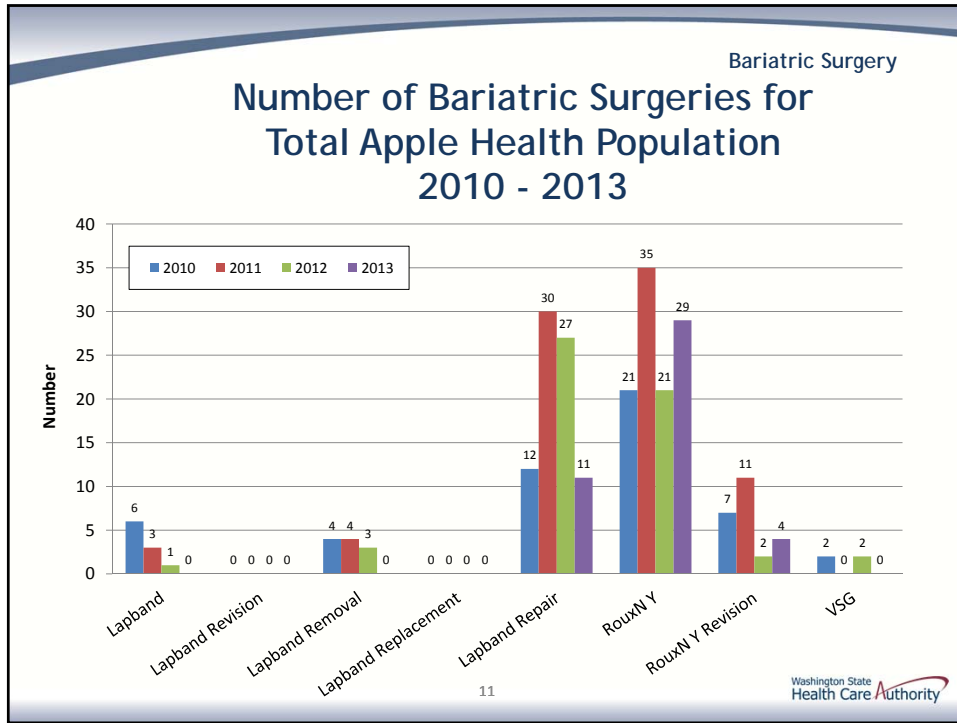
Current State Agency Policy

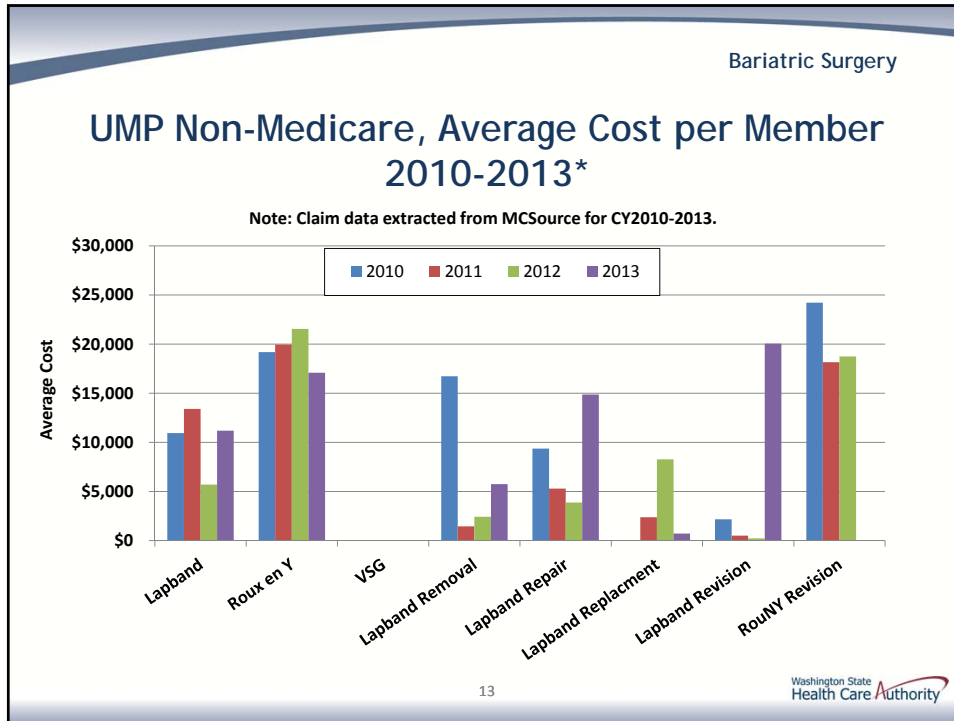
Medicaid

- 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.

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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

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Bariatric Surgery

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

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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

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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

*Flum DR, Belle SH, King WC, et al; Longitudinal Assessment of Bariatric Surgery Consortium. Perioperative safety in the longitudinal assessment of bariatric surgery. N Engl J Med. 2009;361(5):445-454.

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Bariatric Surgery

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

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Bariatric Surgery

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

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Bariatric Surgery

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

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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.

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Bariatric Surgery

Medicare Coverage Decision

2009 NCD:

- RYGB, BPD with DS, and LAGB covered for beneficiaries who meet the following criteria:
 - BMI \geq 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

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Bariatric Surgery

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.

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Bariatric Surgery

State Agency Recommendation: Adults (>21 years)

- Cover for BMI of ≥ 40 without comorbidities
- Cover for BMI of $\geq 35 < 40$ for those patients:
 - With at least 1 obesity related co-morbid condition **AND**
 - Failed medical management
- Non-covered for BMI $\geq 30 < 35$
- 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)

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Bariatric Surgery

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

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Questions?

More Information:

Dan Lessler, MD
Daniel.Lessler@hca.wa.gov

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Order of Scheduled Presentations:

Bariatric Surgery

Name	
1	Robert Michaelson, MD, PhD, FACS, FASMBS President, Washington State Chapter, American Society for Metabolic and Bariatric Surgery Diplomate, American Board of Obesity Medicine

Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of \$10,000.		✓
2.	Equity interests such as stocks, stock options or other ownership interests.		✓
3.	Status or position as an officer, board member, trustee, owner.		✓
4.	Loan or intellectual property rights.		✓
5.	Research funding.		✓
6.	Any other relationship, including travel arrangements.		✓

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:


I am a bariatric surgeon, and the current president of the Washington Chapter of the American Society for Metabolic + Bariatric Surgery.

	Potential Conflict Type	Yes	No
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If yes to #7, provide name and funding Sources: *I am representing the Washington Chapter of the American Society for Metabolic and Bariatric Surgery. I am not being compensated in any way for these efforts.*

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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  4/30/15 Robert Michaelson
 Signature Date Print Name

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

Email Address: rmichaelson@nwwls.com

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WA –ASMBS Public Comments: Washington State Health Care Authority Health Technology Assessment

Bariatric Surgery

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

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FINAL APPRAISAL DOCUMENT

Bariatric Surgery

April 10, 2015

Barbara A. O'Connell, PhD
Chief Review Officer
Christopher J. Colaneri, MD
Senior Review Officer
Anna M. Liso, MA
Research Associate
Patricia E. Swartz, MD, MS
Research Associate
Heather D. Parsons, MD, MS
President

SOS Should Not Have Been Excluded

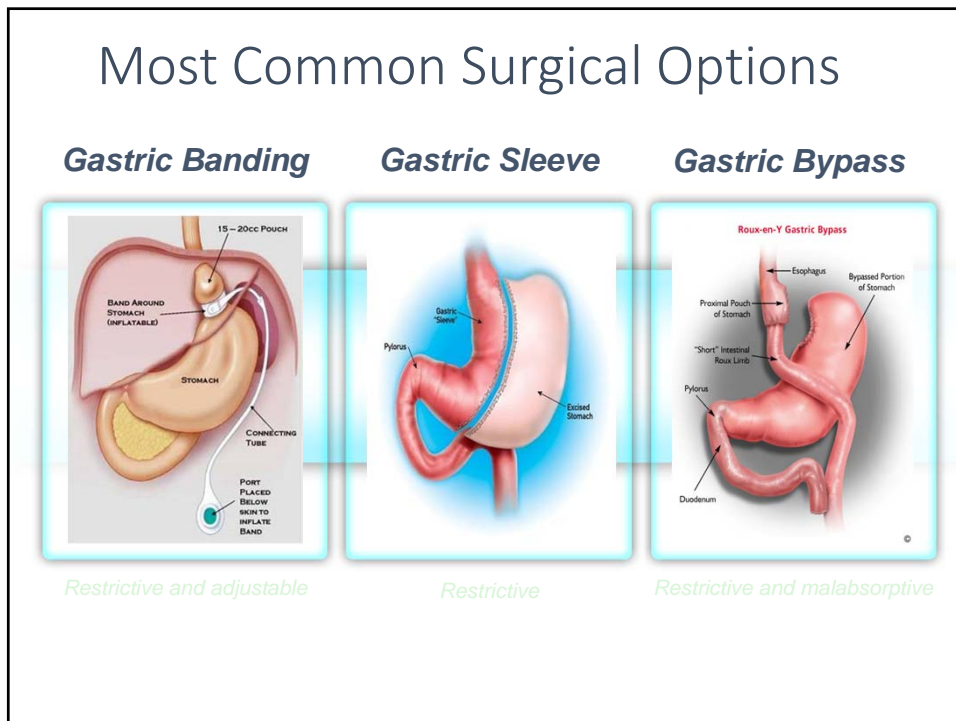
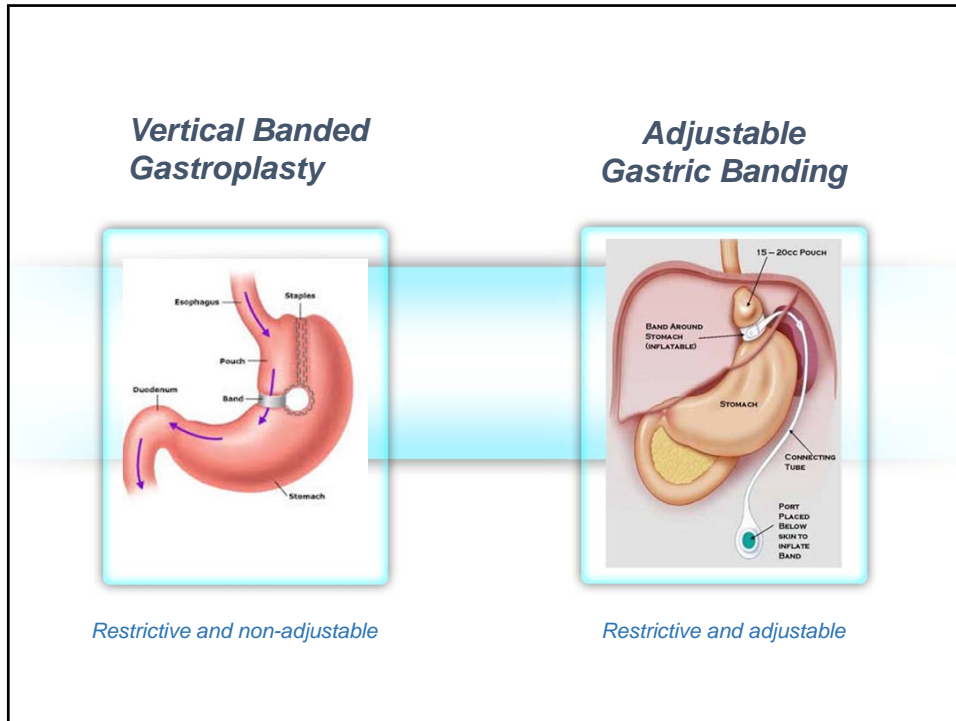
Attrition of the sample also appeared to be a common concern across studies, from small single-center evaluations to large registry studies. Even the widely-cited Swedish Obese Subjects (SOS) study, a matched prospective examination of bariatric surgery and nonsurgical management, saw a precipitous drop-off 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

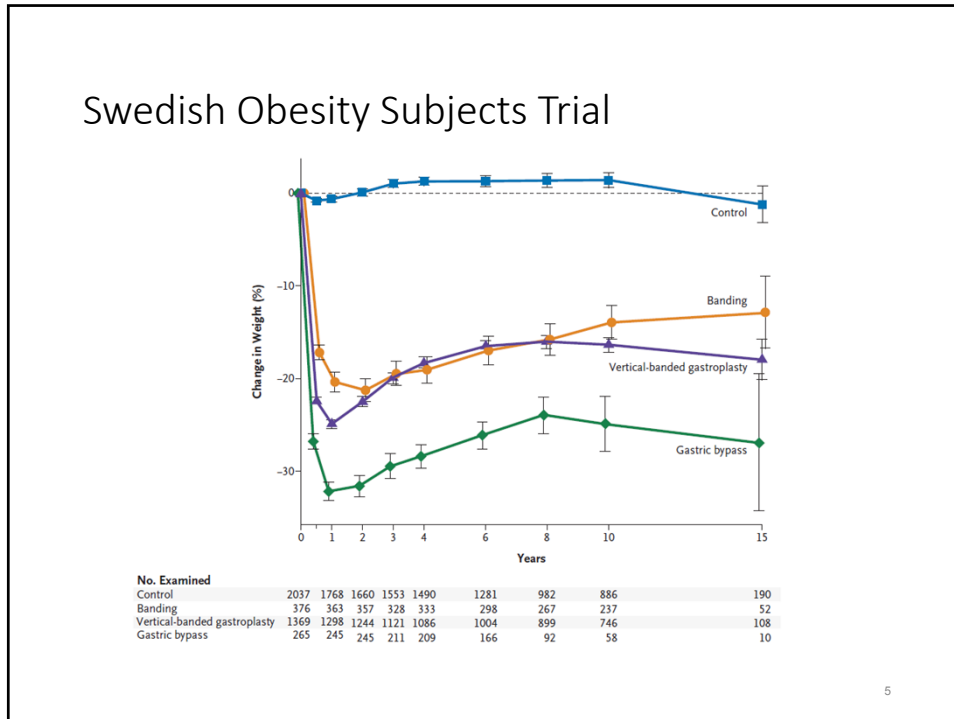
Bariatric Surgery: Draft Evidence Report

ES - 7

- WA-ASMBS considers this exclusion inappropriate

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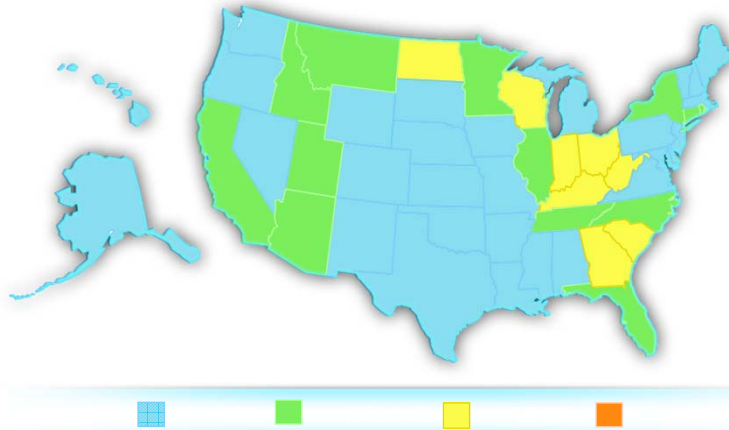
ASMBS Position

Exclusion of SOS is inappropriate for the following reasons:

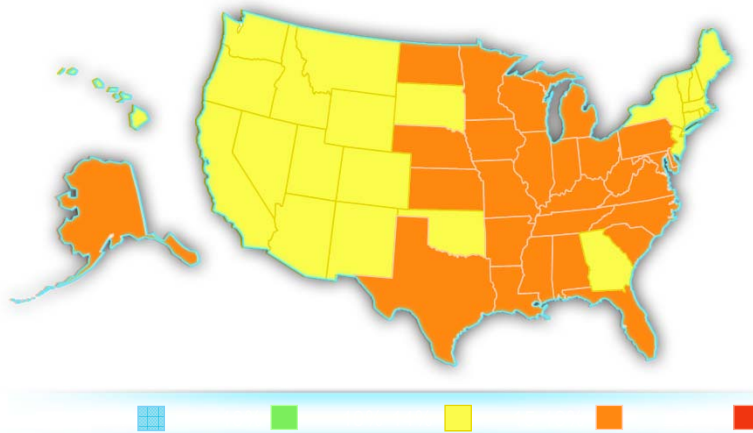
- Weight loss with VBG (approximately 15% long-term) is in the range seen currently with adjustable gastric banding
- The 15% weight loss, while less than that associated with other procedures, still greatly exceeds the weight loss for all non-surgical comparative groups, particularly at two years and beyond
- The SOS trial does provides 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

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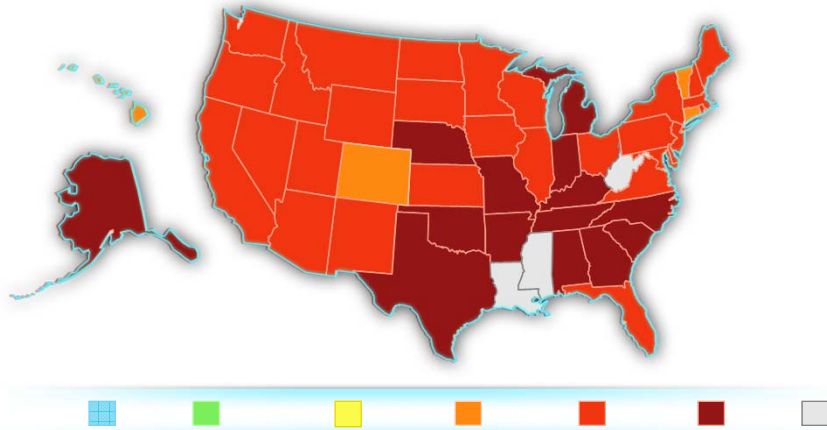
1985 Obesity* Trends Among U.S. Adults



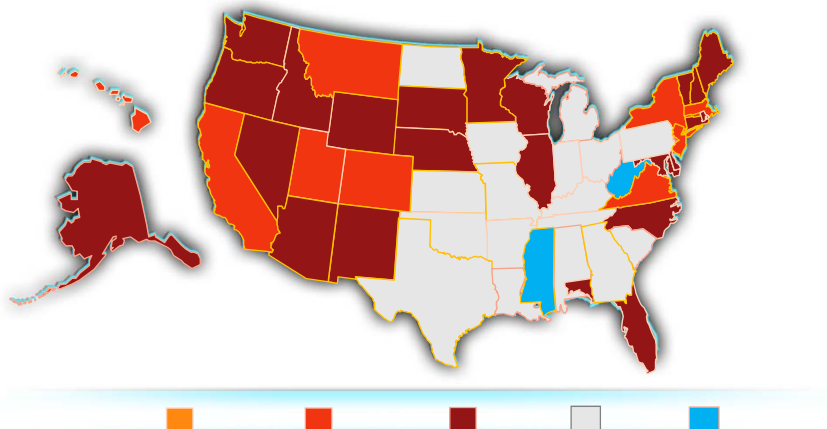
1995 Obesity* Trends Among U.S. Adults



2005 Obesity* Trends Among U.S. Adults



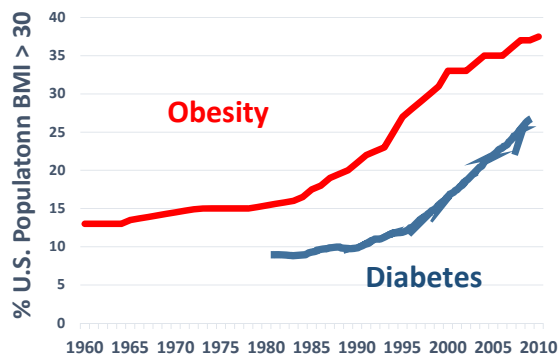
2013 Obesity* Trends Among U.S. Adults



Obesity Prevalence

Despite 30 years of:

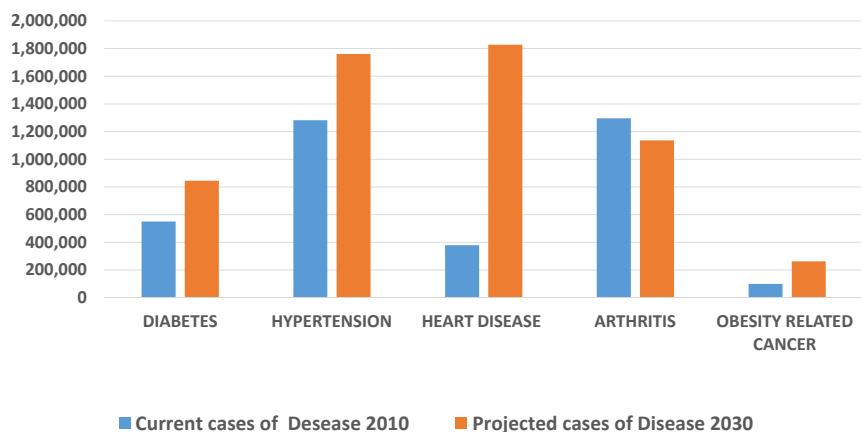
- Diet
- Exercise
- Behavioral Modification



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

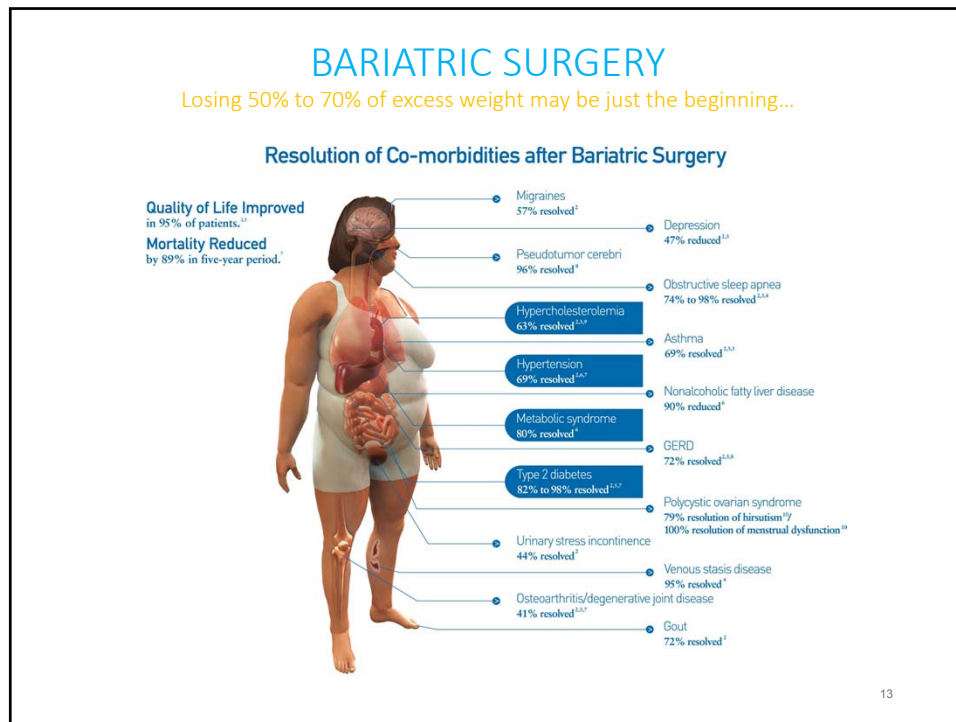
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Washington Obesity Related Disease 2010 - Projected 2030



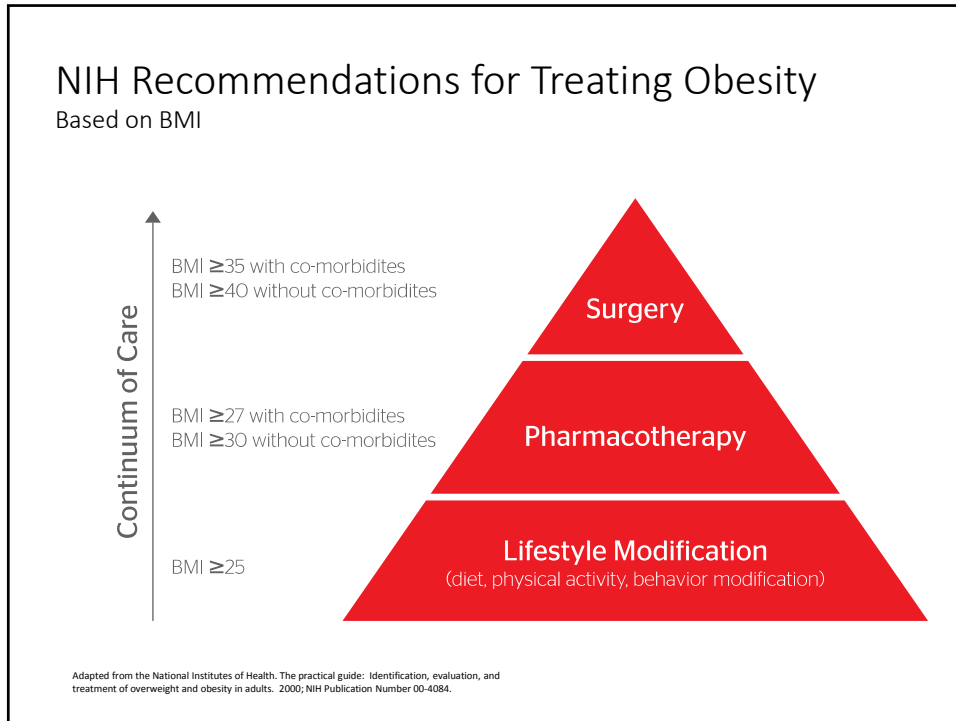
<http://stateofobesity.org/states/wa/>

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- AMA officially recognized obesity as a disease June 19, 2013.

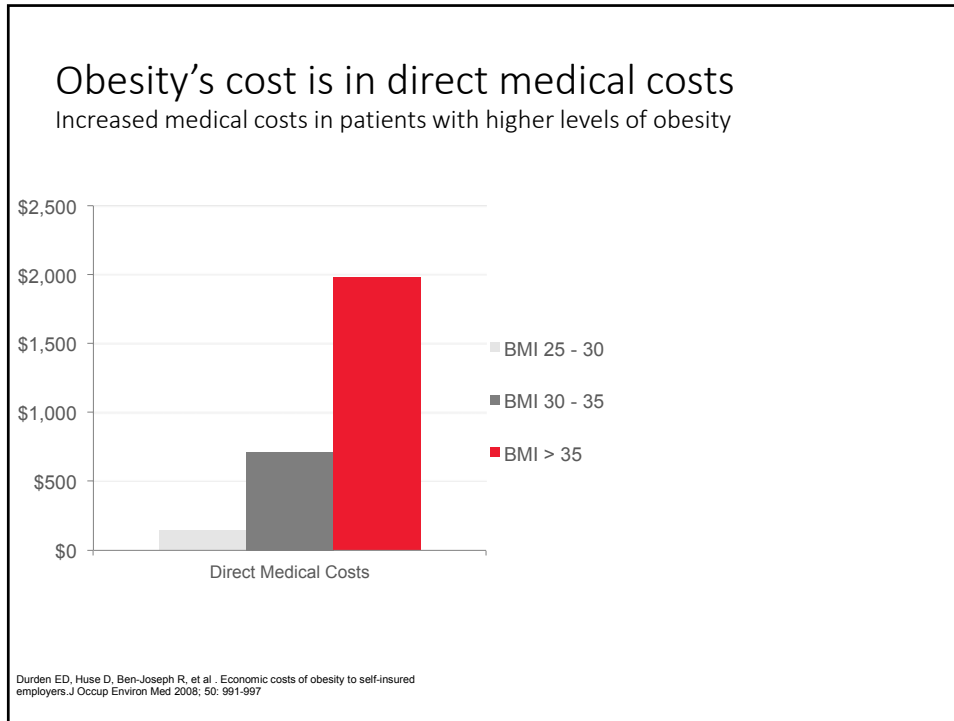




A growing consensus favors bariatric surgery

- “Bariatric surgery should be considered for adults with BMI ≥ 35 kg/m² 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.”
 - The Endocrine society (2012)

Sources: American Diabetes Association. Standards of medical care in diabetes – 2009. Diabetes Care 2009; 32(S1):S13-S61.
 Poirier P, Cormier M-A, Mazzone T et al. Bariatric surgery and cardiovascular risk factors: A scientific statement from the American Heart Association. Circulation 2011; 123:00-00.
 International Diabetes Federation. Bariatric surgical and procedural interventions in the treatment of obese patients with type 2 diabetes. 2011.
 Handelsman Y, Mechanick JL, Blone L et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for developing a diabetes mellitus comprehensive plan. Endocr Prac 2011; 17(Suppl 2).
 page 16

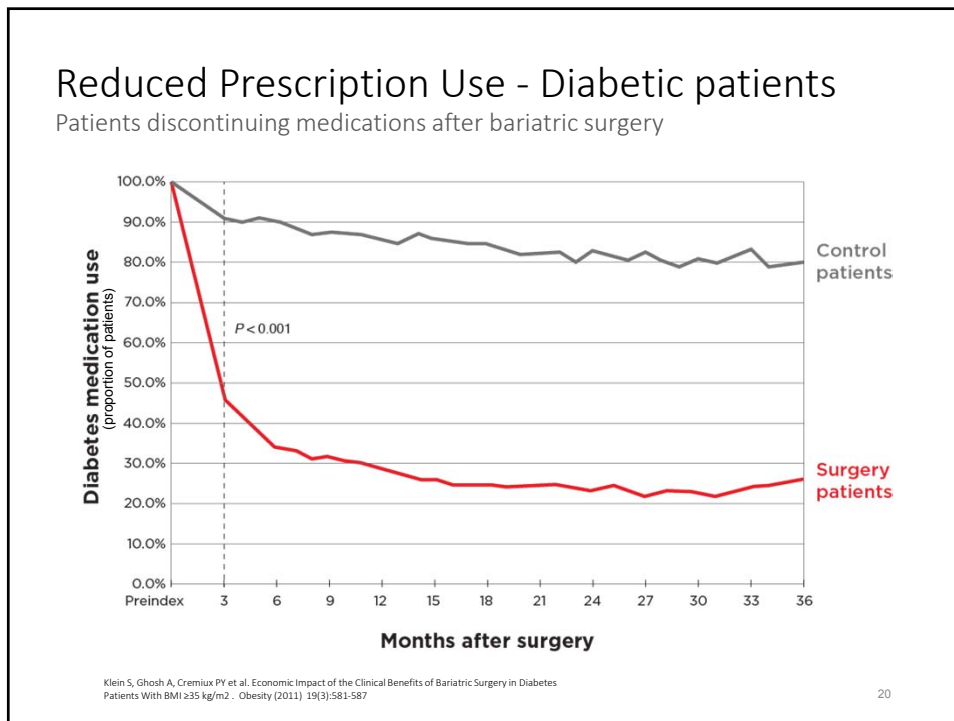
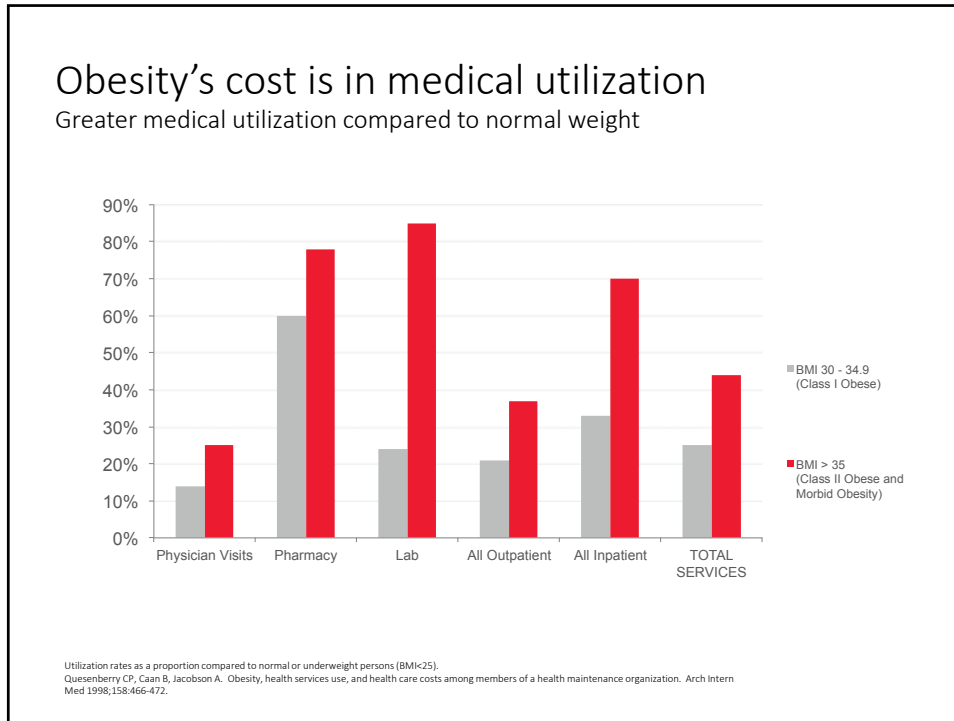


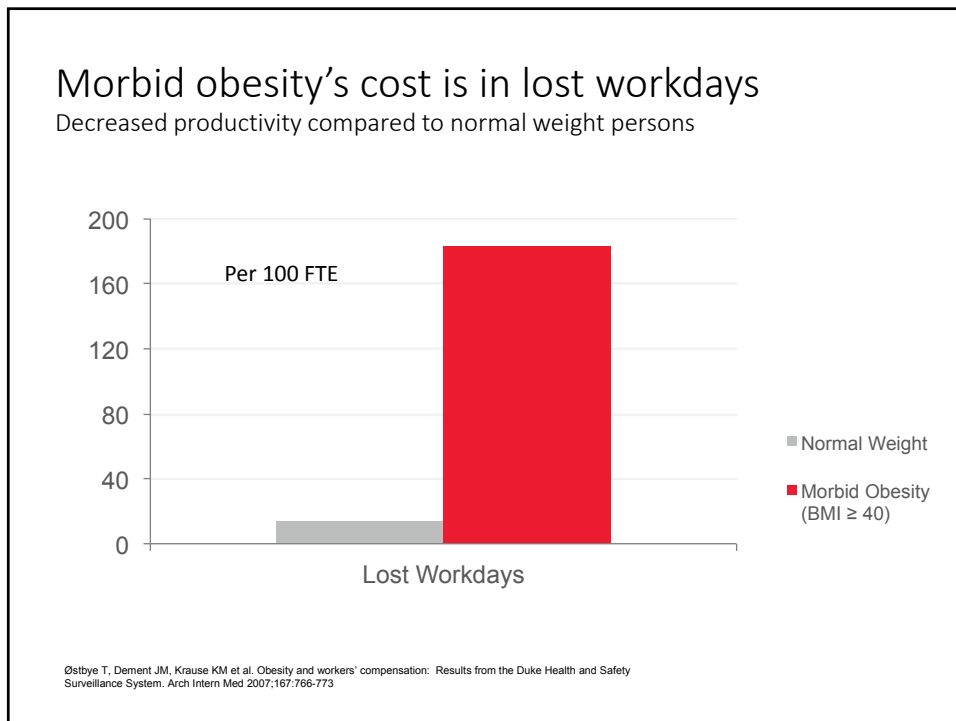
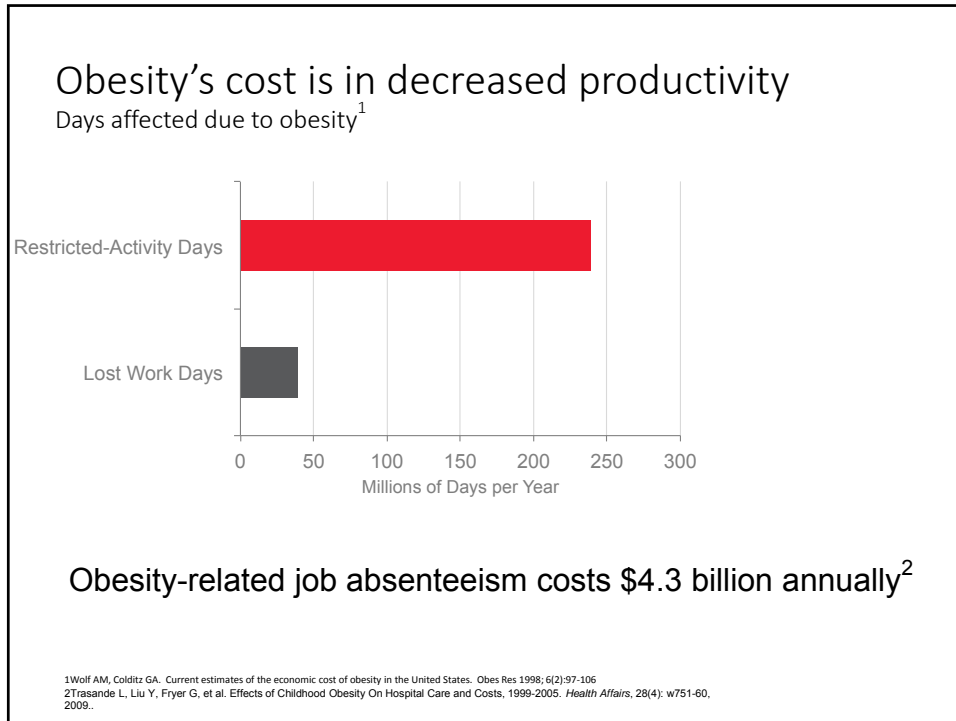
Economics: Direct Costs

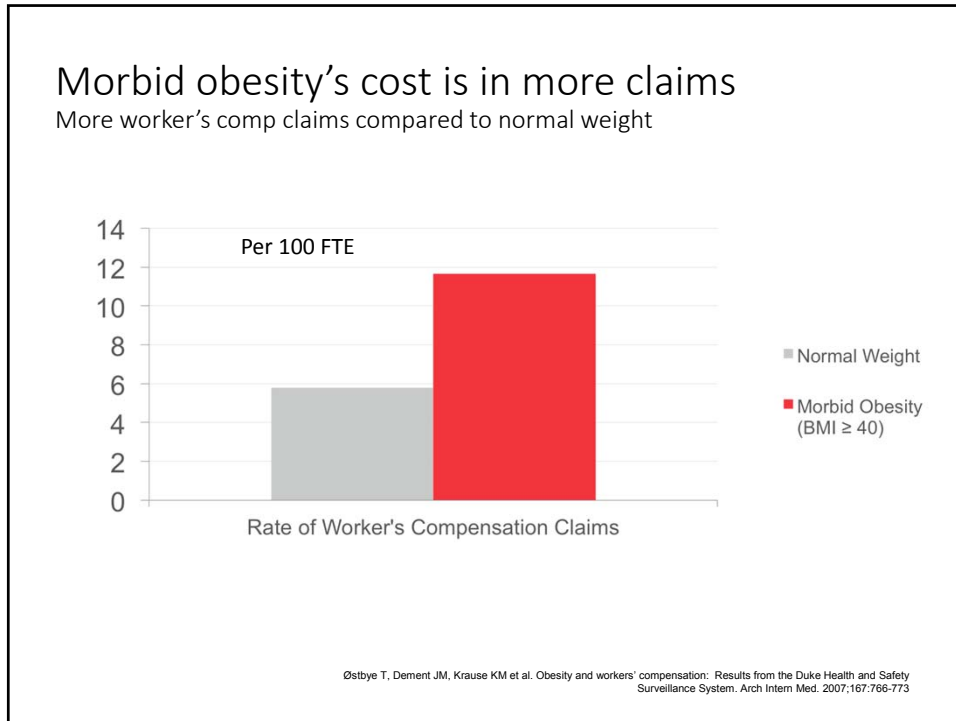
	2008	2018
United States	\$164 Billion (10%)	\$344 Billion (21%)
Washington	\$1.59 Billion	\$7.23 Billion

- Assuming obesity rates continue at their current level

The Future Costs of Obesity: National and State Estimates of the Impact of Obesity on Direct Health Care Expenses. www.americashealthcarerankings/2009/spotlight.aspx







Current Approach to Obesity

254 lbs BMI 42

- 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

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Desirable Approach



2595lbs BMI#26

- 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

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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

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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

2



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 billion in healthcare costs in U.S.
- Historical treatment options limited in effectiveness (lifestyle changes) and/or restricted by safety concerns (older weight-loss medications)

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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

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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

5 *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)

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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.)?

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Key Questions

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

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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?

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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

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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

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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)

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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

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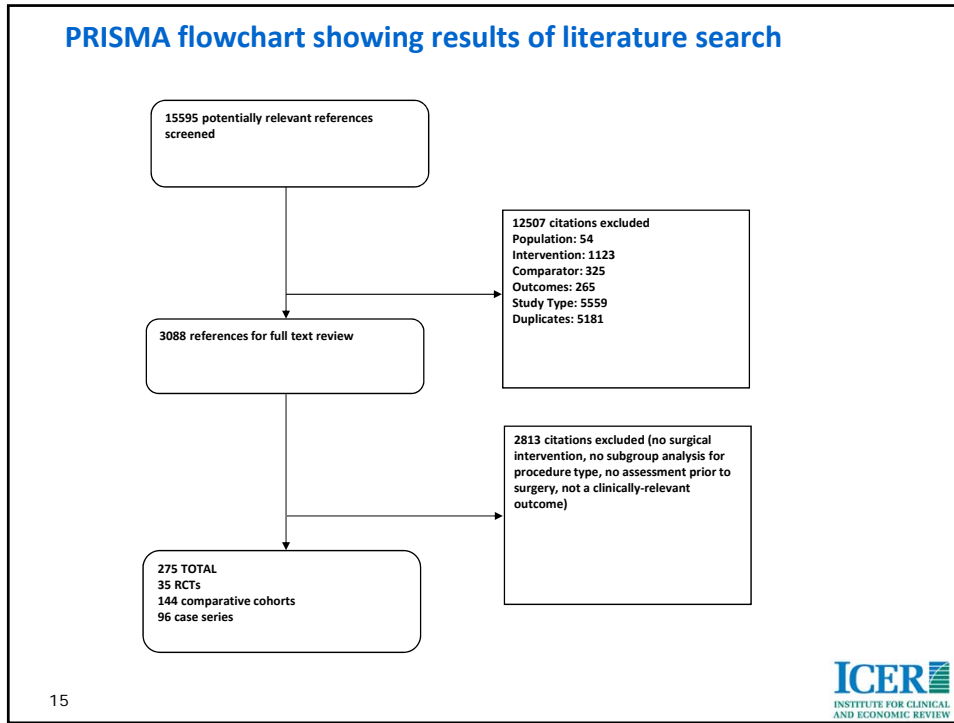


Study Quality/Strength of Evidence

- 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

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Findings

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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


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KQ1a: Effectiveness of Bariatric Surgery in Adults

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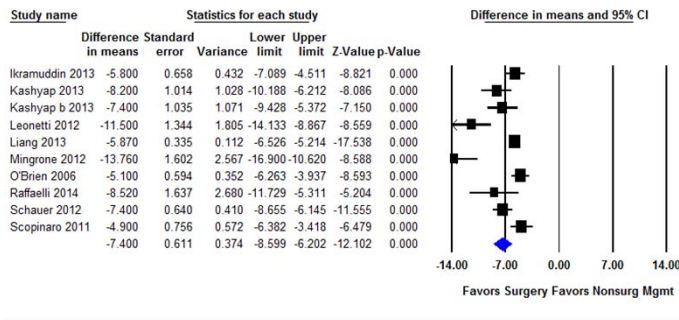


Study Information	Comparators	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence	Direction of Effect	Comments
KQ1a: Effectiveness of Bariatric Surgery in Adults								
Surgery N=2,083 RCT=14	Nonsurg Mgmt	Medium	Consistent	Direct	Precise	+++ Moderate	<i>Incremental</i> Mean reduction in BMI: 7.4 Likelihood of T2DM resolution: log OR 3.6	Benefits also seen with BMI 30-34.9, primarily with T2D resolution
VSG N=1,461 RCT=6	RYGB	Medium	Consistent	Direct	Precise	+++ Moderate	<i>Comparable</i> No significant BMI differences	Limited data on comorbidity resolution
LAGB N=3,111 RCT=2	RYGB	Medium	Consistent	Direct	Precise	+++ Moderate	<i>Inferior</i> >BMI change and EWL for RYGB	Evidence mixed for comorbidity resolution
BPD/DS N=216 RCT=3	RYGB	Medium	Consistent	Direct	Precise	+++ Moderate	<i>Incremental</i> Reduction in BMI of 6-7 pts for BPD	Limited data on comorbidity resolution
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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

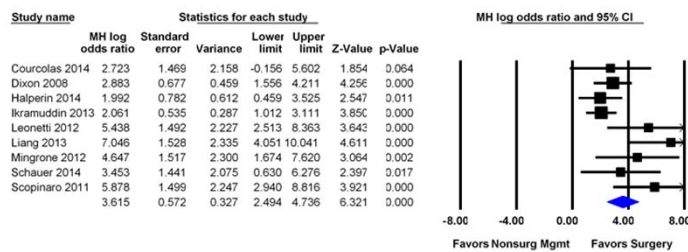


Heterogeneity: Tau²= 2.81; Q=55.8; df=9; I²=84%
 Test for overall effect: Z=-12.1 (p<0.001)

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Resolution of Type 2 Diabetes



Heterogeneity: Tau²= 1.58; Q=20.5; df=8; I²=61%
 Test for overall effect: Z=6.32 (p<0.001)

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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

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Weight-related Outcomes in Patients with BMI <35

Procedure	% Decrease BMI		%EWL	
	Median	Range	Median	Range
RYGB	25.4	(19.6-34.3)	70.0	
VSG	21.3	(21.3-21.3)		
LAGB	16.8	(11.8-21.7)	87.2	
BPD/DS	31.8	(17.3-46.3)		
Follow-up (months)	12.0	(3.0-45.2)	18.0	(12.0-24.0)
No. Studies	7		2	
Good/Fair/Poor	2/3/2		1/0/1	

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KQ1b: Effectiveness of Bariatric Surgery in Pediatric Populations



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Study Information	Comparators	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence	Direction of Effect	Comments
KQ1b: Effectiveness of Bariatric Surgery in Pediatric Populations								
Adolescents Surgery N=50 RCT=1	Nonsurg Mgmt	Medium	N/A	Direct	Imprecise	++ Low	Incremental Mean reduction in BMI: 9.6	Complete resolution of metabolic syndrome in surgical arm
VSG	RYGB	<i>NO STUDIES</i>						
LAGB N=890 RCT=0	RYGB	High	N/A	Direct	Imprecise	+ Insufficient		Groups differed significantly at baseline; no differences after adjustment
BPD/DS	RYGB	<i>NO STUDIES</i>						
Children (<12)		<i>NO STUDIES</i>						



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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

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Study Information	Comparators	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence	Direction of Effect	Comments
KQ2: Components of Bariatric Surgery Management Correlated with Treatment Success								
Surgery	By procedure and vs. nonsurgical mgmt	High	Inconsistent	Indirect	Imprecise	+ Insufficient		Limited evidence suggesting correlation with: *Post-procedure support groups *Team care including dietician *Psychosocial stability

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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

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KQ3: Potential Harms of Bariatric Surgery



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Study Information	Comparators	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence	Direction of Effect	Comments
KQ3: Potential Harms of Bariatric Surgery								
Peri-operative Mortality	Total of 32 studies reporting harms (N=31,637)	High	Inconsistent	Indirect	Imprecise	+ Insufficient		Underreported (75 deaths in 32 studies)
Overall Complications		High	Inconsistent	Direct	Imprecise	++ Low	Median by proc: RYGB: 19.4 VSG: 9.5 LAGB: 17.9 BPD: 31.6	Inconsistent reporting and categorization of complications; RCTs underpowered to detect differences
Reoperation		High	Inconsistent	Direct	Imprecise	++ Low	Median by proc: RYGB: 6.0 VSG: 2.0 LAGB: 14.8 BPD: 13.0	Inconsistent reporting and categorization of reoperations; RCTs underpowered to detect differences



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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

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Potential Harms of Bariatric Surgery

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

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

*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

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Potential Harms of Bariatric Surgery

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

Procedure	# of Studies	# of Patients	Follow-Up; Range, Median (Months)	Complication Rate; Range, Median (%) [‡]	Reoperation Rate; Range, Median (%)	Mortality Rate; Range, Median (%)
BPD	9	2,659	3-63 (24)	8-83, 26.9	0-30, 3.6	0-2.9, 1.40
LAGB	17	16,335	3-72 (29)	0-53, 10.1	0-44, 7.4	0-2.0, 0.15
RYGB	23	840,895	2-72 (29)	0-78, 9.2	0-22, 5.8	0-4.3, 1.94
VSG	11	16,574	2-63 (23)	0-80, 8.8	0-17, 3.9	0-3.9, 0.07

[‡]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

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

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Study Information	Comparators	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence	Direction of Effect	Comments
KQ4: Differential Effectiveness and Safety According to Health-System or Program Factors								
Surgeon Experience	N/A	High	Consistent	Direct	Imprecise	++ Low	Improvement in outcomes after 68-250 cases	Variable estimates by study and procedure
Procedure Volume	N/A	Medium	Consistent	Direct	Imprecise	++ Low	Lower complication rates, better weight loss at surgeon or hospital volume >50-200 cases	Variable estimates by study and procedure
Certification/Accreditation	Non-COE facilities	High	Inconsistent	Indirect	Imprecise	++ Low	Mixed evidence of benefit at COE vs. non-COE facilities	One comparative study, other posttest evaluations after Medicare NCD
Core Team Members	Surgical team only	High	Inconsistent	Indirect	Imprecise	++ Low	Some data suggest multidisciplinary care superior to surgical team only	Confounded by COE requirements that bariatric care be multi-disciplinary
Pre/Post Procedure Support	Multiple	Medium	Inconsistent	Direct	Imprecise	++ Low	No effect of pre-operative weight loss or dietary counseling; post-operative dietary counseling and support more effective	Problematic to compare variable approaches across studies

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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

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KQ5: Differential Effectiveness and Safety by Patient Factors



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Study Information	Comparators	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence	Direction of Effect	Comments
KQ 5: Differential Effectiveness and Safety According to Patient Factors								
Demographics	N/A	Medium	Inconsistent	Direct	Imprecise	++ Low	No consistent effects of age, gender, or race	
BMI	N/A	High	Consistent	Direct	Imprecise	++ Low	Best outcomes for BMI ≥40 vs. 30-39 and 50+	Comparison problematic across studies due to limited subgroup data
Comorbidities/ Prior Events	N/A	High	Inconsistent	Indirect	Imprecise	++ Low	Cardiac comorbidities affect RYGB outcomes more than LAGB	
Smoking Status	<i>NO STUDIES</i>							
Psychosocial Health	<i>NO STUDIES</i>							
Program Adherence	N/A	High	Inconsistent	Indirect	Imprecise	+ Insufficient	EWL lower in LAGB with poor pre-op program adherence; no effect for RYGB	Single retrospective cohort



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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

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KQ6: Costs and Cost-Effectiveness of Bariatric Surgery

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Study Information	Comparators	Risk of Bias	Consistency	Directness	Precision	Strength of Evidence	Direction of Effect	Comments
KQ 6: Costs and Cost-Effectiveness of Bariatric Surgery								
Surgery	Nonsurg Mgmt	Medium	Consistent	Indirect	Imprecise	+++ Moderate	\$2,000-\$30,000 per QALY	Variable data sources and assumptions
VSG	RYGB	Medium	Inconsistent	Indirect	Imprecise	++ Low	Less expensive but slightly less effective	Data only from ICER model
LAGB	RYGB	Medium	Consistent	Indirect	Imprecise	+++ Moderate	Less expensive and less effective	Variable data sources and assumptions
BPD/DS	RYGB	Medium	Inconsistent	Indirect	Imprecise	++ Low	\$65,000-\$97,000 per QALY	Data only from ICER model


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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

44 *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)

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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

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Cost-Effectiveness of Bariatric Surgery, 10-year Timeframe (BMI 30+)

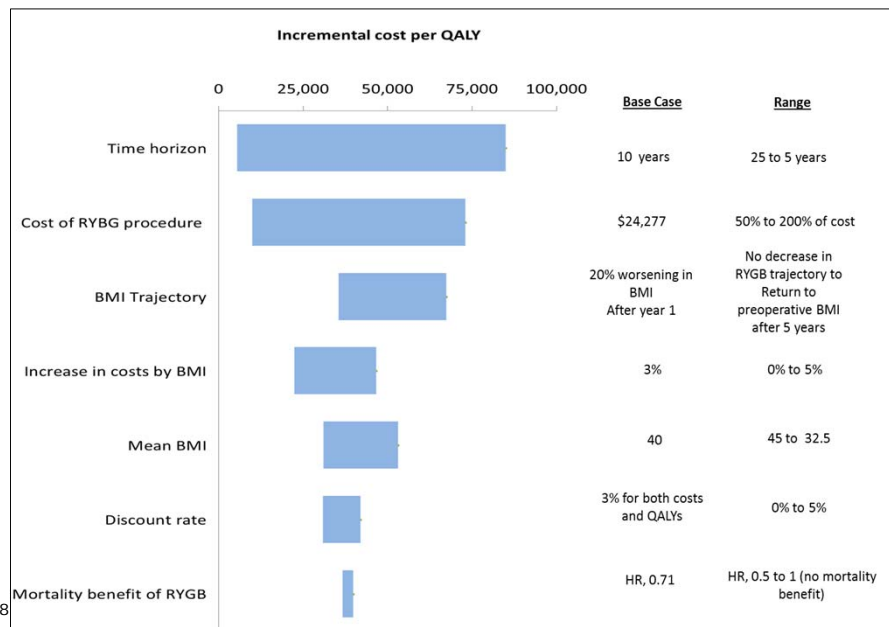
BMI Level/ Procedure	Cost (\$)	Effectiveness (QALYs)	Cost-effectiveness (\$/QALY gained)	
			Vs. SC	Vs. RYGB
BMI ≥ 30				
Standard care	\$34,923	7.5680	NA	NA
RYGB	\$54,110	8.0807	\$37,423	NA
VSG	\$48,702	8.0417	\$29,087	Less expensive & less effective
LAGB	\$47,668	7.9252	\$35,680	Less expensive & less effective
BPD/DS	\$65,741	8.2307	\$46,508	\$77,574

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)

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Sensitivity Analyses



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Integrated Evidence Ratings



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ICER Rating Matrix

<i>Comparative Clinical Effectiveness</i>	Superior: A	Aa	Ab	Ac
	Incremental: B ⁺ /B	B ⁺ a Ba	B ⁺ b Bb	B ⁺ c Bc
	Comparable: C ⁺ /C	C ⁺ a Ca	C ⁺ b Cb	C ⁺ c Cc
	Inferior: D	Da	Db	Dc
	Promising but Inconclusive: P/I	Pa	Pb	Pc
	Insufficient: I	I	I	I
		a High	b Reasonable/Comp	c Low
		<i>Comparative Value</i>		



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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

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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

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Clinical Practice Guidelines

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Practice Guidelines

- AHA, ACC, TOS, AACE, ASMBS, VA/DoD (Adults)
- Consistent support for bariatric surgery for BMI ≥ 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 ≥ 50 or ≥ 40 with severe comorbid conditions and failure of lifestyle/medical intervention

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Payer Coverage Policies

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CMS

- 2009 NCD; coverage for:
 - BMI ≥ 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

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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 \pm DS investigational and does not cover it

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Appendix: Quality Criteria

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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

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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-effective¹ as expressed by the following standards²:

- 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 harms³:

- 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.

¹Based on Legislative mandate: See RCW 70.14.100(2).

²The principles and standards are based on USPSTF Principles at: <http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm>

³The 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 evidence⁴ 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.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

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>

and coverage decision. 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?

Outcomes	Evidence
Safety	Safety
Death	
Reoperation/revision/removal	
Other medical complication(s)	
Efficacy – Effectiveness	Efficacy / Effectiveness
Decrease in BMI	
Excess Weight Loss	
Improved Type II DM	
Improved other comorbidities	
Special Population / Considerations	Special Populations/ Considerations
Age	
Race/ethnicity	
Comorbidities	

Psychosocial health	
Program adherence	
Surgical experience/Procedure volume	
Pre/post surgery support	
Cost	Cost
Cost	
Cost-effectiveness	
Cost-utility	

**Medicare Coverage and Guidelines
[FROM PAGE 10 OF FINAL EVIDENCE REPORT]**

<http://www.cms.gov/medicare>

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/m², or with a BMI of at least 35kg/m² 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/m².

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 $\geq 40\text{kg/m}^2$ who do not have existing medical complications and for whom surgery would not pose excessive risk. Patients with a BMI $\geq 35\text{kg/m}^2$ 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/m² 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.

U.S. Department of Veteran's Affairs/Department of Defense (VA/DoD) (2014)

<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/m² or with a BMI of 35.0-39.9kg/m² 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/m². 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/m². 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 $\geq 40\text{kg/m}^2$ or $\geq 35\text{kg/m}^2$ 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 50kg/m^2 , or with a BMI above 40kg/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 $\geq 40\text{kg/m}^2$ or $\geq 35\text{kg/m}^2$ 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 $>50\text{kg/m}^2$ in whom other interventions have not been effective. Expedited surgical assessment may be considered for patients with BMI $\geq 35\text{kg/m}^2$ with recent-onset type 2 diabetes. Patients with BMI between 30 and 34.9kg/m^2 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>

Bariatric surgery is suggested for adults with clinically severe obesity, characterized by a BMI of $\geq 40\text{kg/m}^2$ or $\geq 35\text{kg/m}^2$ 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 \pm 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.

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:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective				
Safe				
Cost-effective				

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.